Missouri Board of Pharmacy

Missouri Pharmacy Practice Guide

February | 2013

MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the ***Missouri Pharmacy Practice Guide.*** The ***Pharmacy Practice Guide*** is designed to increase licensee compliance by providing guidance on basic provisions of Missouri's law governing the pharmacy profession.

The Missouri Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Insurance, Financial Institutions and Professional Registration. The Board consists of seven (7) members, including, one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri. Since 1909, the Missouri Board of Pharmacy has served Missouri citizens through the regulation and licensing of the pharmacy profession.

The Board's mission is to serve and protect the public in the practice of pharmacy by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetency, misconduct, gross negligence, fraud, misrepresentation and dishonesty;
- Licenses only qualified professionals by examination and evaluation of minimum competency; and
- Enforces practice standards by implementing legislation and adopting administrative rules.

Additional pharmacy resources and compliance materials are available on the Board's website at http://pr.mo.gov/pharmacists. The Board also provides license and regulatory updates via e-alerts and the Board's electronic newsletter. To sign up for the Board's newsletter and e-alerts, visit www.nabp.net/indexmobop.asp or e-mail MissouriBOPNewsletter@nabp.net.

The Missouri Pharmacy Practice Guide is provided for informational purposes only. The Practice Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should thoroughly review Chapter 338, RSMo, 20 CSR 2220 and all other applicable state and federal laws. The Practice Guide does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board of Pharmacy expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document may be addressed to the Board office.

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SECTION A: REGULATORY AUTHORITY

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A.1 General Authority

The Board is governed by the Missouri Pharmacy Practice Act enacted in Chapter 338 of the Revised Statutes of Missouri (RSMo). Pursuant to Chapter 338, the Board has primary regulatory authority over the practice of pharmacy in Missouri. The Board's duties include, but are not limited to,:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/regulating pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors and drug distributor registrants;
- Investigating complaints, and;
- Inspecting pharmacies and drug distributors.

The Board's administrative rules are promulgated in Chapter 20 CSR 2220 of the Missouri Code of State Regulations.

The Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") regulates controlled substance distribution in Missouri. However, the Board actively monitors and inspects compliance with applicable controlled substance drug laws. For questions regarding controlled substance registration, contact BNDD at (573) 751-6321 or at bndd@health.mo.gov.

The Board does not have jurisdiction over in-patient hospital pharmacy services that are not provided by a Missouri licensed pharmacy. For questions regarding in-patient hospital pharmacy services, please contact the Missouri Department of Health and Senior Services, Bureau of Health Services Regulation at (573) 751-6303.

A.2 Discipline

The Board may discipline a licensee or registrant for any grounds identified in § 338.055.2. Disciplinary action may be taken if any licensee or registrant has, or any officer, owner, pharmacist-in-charge or manager-in-charge has, committed any of the following:

1. Use of any controlled substance, as defined in Chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;
2. The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;
3. Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;
4. Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

5. Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
6. Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
7. Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;
8. Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;
9. A person is finally adjudged incapacitated by a court of competent jurisdiction;
10. Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter. *Note: This includes unlawfully allowing an unregistered technician to assist in the practice of pharmacy*;
11. Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;
12. Failure to display a valid certificate or license if so required by [Chapter 338] or any rule promulgated [t]hereunder;
13. Violation of any professional trust or confidence;
14. Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;
15. Violation of the drug laws or rules and regulations of this state, any other state or the federal government;
16. The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs; or
17. Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

Disciplinary action may include, but is not limited to, public censure, probation, suspension or revocation. If revoked, the Board may statutorily prohibit a licensee from reapplying for licensure for up to seven (7) years.

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SECTION B: PHARMACIST LICENSING

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B.1 General Requirements

No person may perform, or offer to perform, the "practice of pharmacy" in the state of Missouri without a current and active Missouri pharmacist license. Section 338.010.1, RSMo, defines "the practice of pharmacy" as:

- The interpretation, implementation, and evaluation of medical prescription orders, including, receipt, transmission, or handling of such orders or facilitating the dispensing of such orders;
- The designing, initiating, implementing, and monitoring of a medication therapeutic plan for a specific patient, as defined by rules of the Board;
- Compounding, dispensing, labeling, and administering drugs/devices pursuant to a medical prescription order;
- Administering influenza, pneumonia, shingles and meningitis vaccines by protocol;
- Participation in drug selection and drug utilization reviews according to state law;
- The proper and safe storage of drugs and devices and the maintenance of proper records;
- Consultation with patients and other health care practitioners about the safe and effective use of drugs and devices; and,
- Offering or performing any act, service, operation, or transaction necessary in the conduct, operation, management and control of a pharmacy. [§ 338.010]

This definition does not apply to, or interfere with, legally registered practitioners of medicine, dentistry, podiatry, veterinary medicine or optometrists that are compounding or dispensing their own prescriptions, as authorized by governing law. [§ 338.010.1]

▶ *Immunizations/Administration By Prescription Order:* In addition to Missouri's licensure requirements, pharmacists must file a Notification of Intent with the Board prior to immunizing or administering medication by prescription order. Pharmacists who immunize or administer medication by prescription order without a valid Notification of Intent on file with the Board may be subject to discipline. *See also Section I (Immunizations) and Section J (Administration).*

▶ *Medication Therapy Services (MTS):* In 2007, Chapter 338, RSMo, was amended to authorize pharmacists to perform medication therapy services with a certificate of medication therapy services issued by the Board. See *Section K* for additional information on obtaining a MTS certificate and other MTS requirements.

> *The Board may restrict or limit licensees under discipline from immunizing, administering medication by protocol or providing medication therapy services.*

B.2 Renewals/Continuing Education

Pharmacist licenses are renewed biennially in even numbered years (i.e.- 2010, 2012, 2014, etc). To renew, pharmacists must file a renewal application with the required fee and complete 30 hours of approved continuing education (CE). [20 CSR 2220-2.100]. Continuing education must have been

earned between September 1st of the prior renewal period and August 31st of the current renewal year. [20 CSR 2220-2.100]. For example, licensees renewing in 2010 must have completed 30 hours of continuing education from September 1, 2008, to August 31, 2010. The Board randomly audits CE compliance. Licensees must retain proof of CE compliance for two renewal cycles and produce CE documentation, as requested by the Board.

> *Pharmacists that were licensed on or after February 1st of a renewal year are required to renew but are exempt from the CE requirements for that renewal cycle.*

B.3 Change Of Address/Employment

To ensure sufficient communication, pharmacists should immediately notify the Board of address changes. [20 CSR 2220-2.010(1)(N)]. Correspondence returned to the Board because of an incorrect address will not be sent out a second time until a correct address is provided. Notification of employment changes must be submitted to the Board no later than fifteen (15) days after the effective date of the change. [20 CSR 2220-2.010(1)(Q)]. Address and employment changes may be submitted online via the Board's website, by faxing (573) 526-3464 or by writing the Board office.

B.4 Jury Duty

Section 494.430.1(4), RSMo, authorizes health care providers, including pharmacists, to be excused from jury duty if he/she is actually providing health care services to patients, and service as a juror would be detrimental to the health of the person's patients. *See § 494.430.1(4) for additional information.*

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SECTION C: PHARMACY GENERAL STANDARDS

C.1 Pharmacy Licensure

No person or entity may open, establish, operate or maintain a pharmacy in the state of Missouri without a valid Missouri pharmacy permit. Pursuant to § 338.210, a pharmacy is defined as "*any location where the practice of pharmacy occurs*" or where "*such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist*." A pharmacy includes, but is not limited to, any place:

- Where the practice of pharmacy is offered or conducted;
- Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed, sold or offered for sale at retail;
- Where the words "pharmacist", "apothecary", "drugstore", "drugs", and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;
- Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons. [§ 338.210].

A Missouri pharmacy permit is also required to conduct or transact business in Missouri under the name "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist shop", "drug store", "druggist", "drugs", "consultant pharmacist", or any similar word. [§ 338.260].

Pharmacies may be owned by unlicensed persons or entities. However, the practice of pharmacy may only be conducted by licensed pharmacists.

C.2 Pharmacy Classifications

The Board issues the following classes of pharmacy permits [§ 338.220, 20 CSR 2220-2.020(9)]:

- ***Class A (Community/Ambulatory)***: Required to provide pharmacy services to the general public (i.e.- retail).
- ***Class B (Hospital Outpatient Pharmacy)***: Required for pharmacies operated and located within a hospital that provide pharmacy services to anyone other than the hospital's in-patients.
- ***Class C (Long-Term Care)***: Required for pharmacies dispensing drugs/devices to patients residing in a long-term care facility. For purposes of Chapter 338, a long-term care facility is defined as a nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients. *See also Section M*.
- ***Class D (Non-Sterile Compounding)***: Required for pharmacies providing non-sterile compounding as defined by 20 CSR 2220-2.400(3), in batch quantities using bulk active ingredients. [See 20 CSR 2220-2.400 for additional requirements].
- ***Class E (Radiopharmaceutical)***: Required for pharmacies preparing and dispensing radioactive drugs as defined by the Food and Drug Administration (FDA) to health care providers for use in the treatment or diagnosis of disease. Radiopharmaceutical

pharmacies must maintain a qualified nuclear pharmacist. The nuclear pharmacist must be personally present and directly supervise all personnel assisting in drug preparation/dispensing. [See 20 CSR 2220-2.500 for compliance requirements].

- ***Class F (Renal Dialysis)*:** Required for pharmacies dispensing renal dialysis solutions and other drugs/devices associated with dialysis care. Renal dialysis pharmacies may not be open to the general public and may only dispense renal dialysis solutions and renal dialysis associated drugs, supplies or devices. [See 20 CSR 2220-2.600].
- ***Class G (Medical Gas)***: Required for pharmacies providing oxygen and other prescription gases by prescription for therapeutic use.
- ***Class H (Sterile Product Compounding)***: Required for pharmacies providing sterile products, as defined by 20 CSR 2220-2.200.
- ***Class I (Consultant)***: Required for any location where the practice of pharmacy is conducted but which is not being used for the procurement, storage, possession or ownership of any drugs at/from the location.
- ***Class J (Shared Service)***: Required to perform pharmacy services for a Missouri licensed pharmacy, including, filling or refilling a prescription drug, drug utilization review (DUR), claims adjudication, outsourcing centralized prescription processing, refill authorizations, therapeutic interventions or assisting with any other function associated with the dispensing process. A Class J permit is required for all pharmacies involved in shared services. [20 CSR 2220-2.650].
- ***Class K (Internet)***: Required for pharmacies involved in the receipt, review, preparation, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for new prescriptions originated from the internet for more than 90% of the pharmacy's total new prescription volume on any day. *[See the Ryan Haight Act for additional federal requirements]*.
- ***Class L (Veterinary)***: Required for any entity engaged in the sale, dispensing, or filling of a legend drug for use on animals that can only be dispensed by prescription under state or federal law. *Note: Pharmacies with a Class A permit may dispense legend drugs for animals without an additional Class L permit. However, Class A pharmacies should review 20 CSR 2220-2.675 governing standards of operation for Class L Veterinary Pharmacies for additional compliance requirements.*

A pharmacy may only engage in the pharmacy activities allowed for the class(es) reflected on the pharmacy's permit. Pharmacy classifications must be accurately maintained with the Board at all times. [20 CSR 2220-2.020(10)]. To add or delete a class, a notarized change of classification application must be filed with the Board. Pharmacies may not engage in activities associated with an added class until the Board has issued a permit reflecting the new classification.

> *Pharmacies must comply with all regulations pertaining to any class listed on the pharmacy's permit even if they are not performing such activities. For example, a pharmacy with Class H Sterile Product Compounding on their permit must comply with 20 CSR 2220-2.200 Sterile Pharmaceuticals whether they are compounding sterile products or not.*

C.3 General Requirements

To be eligible for a pharmacy permit, applicants must file an application with the Board and pass a Board inspection. Applicants must also meet the following general requirements [20 CSR 2220-2.010(1)(C) – (F), 20 CSR 2220-2.020]:

- The pharmacy must be under the supervision of a "pharmacist-in-charge" who is responsible for ensuring the pharmacy is operating in full compliance with all applicable state and federal laws;
- The pharmacy must be equipped with proper pharmaceutical and sanitation appliances;
- The pharmacy must be maintained in a clean, sanitary and orderly manner. Any compounding, dispensing or admixture must be completed under clean, and if required, aseptic conditions [20 CSR 2220-2.010(1)(F)];
- Equipment and facilities must be operated in a manner that will not endanger the public health or safety;
- Proposed/current operations must comply with Chapter 338 and all applicable provisions of state and federal law; and
- Animals are not allowed in pharmacies, except for service animals as defined by the Americans with Disabilities Act. [20 CSR 2220-2.010(1)(F)]

C.4 Pharmacy Equipment/Refrigeration

Pharmacies must be equipped with proper pharmaceutical equipment and reference manuals for the services rendered. [20 CSR 2220-2.010(1)(C) – (D)]. Equipment requirements will vary depending on the pharmacy's activities. The Board does not approve specific brands or products. However, the following minimum equipment is required:

- Any basic equipment recognized by the latest edition of the *United States Pharmacopoeia* (USP), the *United States Pharmacopoeia/Drug Information* (USP/DI) or *Remington's: The Science and Practice of Pharmacy*;
- A suitable machine/device for numbering prescriptions;
- Printing equipment for producing prescription labels;
- The current or latest edition of a reference manual(s) which includes all FDA approved drugs and information on pharmacology, dosages and clinical effects of drugs, and patient information; and
- A current edition of statutes and rules governing the pharmacy's practice.

> *Reference materials can be maintained electronically or hardbound. However, the materials must be immediately accessible to pharmacy staff and immediately retrievable during an inspection. Pharmacy staff should know how/where to locate materials on request.*

Pharmacies must have adequate refrigeration and sufficient storage space for the pharmacy's drug inventory. Drug storage areas must be thermostatically controlled within the temperature requirement(s) provided by the manufacturer or the latest edition of USP. [20 CSR 2220-2.010(1)(G)]. To ensure compliance, drug storage areas should have a thermometer or other

temperature device to monitor for appropriate temperature. Foods and other items must be stored separately from drugs and drug related items. [20 CSR 2220-2.010(1)(G)]. *Note: Licensees should review package labeling as some products have special storage/temperature requirements and may not be stored in certain refrigeration/freezer units (i.e.- dormitory style refrigerators).*

C.5 Pharmacist-In-Charge

A licensed pharmacist must be designated to serve as "pharmacist-in-charge" ("PIC") of each pharmacy. [20 CSR 2220-2.010(1)(M)]. The PIC is personally responsible for supervising pharmacy activities and for ensuring full compliance with:

- All state and federal drug laws and rules, and;
- All state and federal drug distribution laws and licensing requirements.

Rule 20 CSR 2220-2.090 contains a detailed listing of additional PIC responsibilities/duties. Licensees should carefully review the provisions of 20 CSR 2220-2.090 and Chapter 338, RSMo, before accepting PIC responsibilities. The Board may take disciplinary action against the PIC's personal pharmacist license for pharmacy violations/non-compliance.

A pharmacist may serve as PIC for more than one pharmacy. However, the PIC must be actively engaged in the operation of each pharmacy. Licensees should carefully consider the potential pharmacy volume and the nature of each pharmacy's activities prior to accepting multiple PIC responsibilities.

PIC Changes: A pharmacist is required to immediately notify the Board if he/she stops serving as a designated PIC. [20 CSR 2220-2.010(1)(M)]. The pharmacy may not continue operations until a new PIC has been designated who meets Missouri's requirements. Once designated, the new PIC may begin serving immediately. However, a fully completed *Change of Pharmacist-In-Charge application* must be promptly submitted to the Board to officially complete the change. [20 CSR 2220-2.010(1)(M)]. Documentation of the application mailing date should be maintained in the pharmacy's records. Applications not received by the Board in a timely fashion may result in the PIC designation being voided or other disciplinary review/action.

The permitholder and the new pharmacist-in-charge are responsible for completing an inventory of controlled substances at the time of a PIC change. [20 CSR 2220-2.090(2)(T)]. The inventory must include all Schedule II through V controlled substances, including, Schedule V pseudoephedrine-containing over-the-counter products. Documentation of the required inventory must be maintained in the pharmacy's records. To ensure accuracy, the Board recommends the former and new pharmacist-in-charge jointly take the required inventory.

C.6 Pharmacy Supervision

A pharmacist must be present and on duty at all times when the pharmacy is in operation or when prescriptions are being compounded, prepared, distributed or dispensed. Pharmacy technicians may assist in any area of pharmacy practice, including, receiving, preparing, compounding, distributing or dispensing prescriptions. However, technicians may not work independently and must be under the "direct supervision and responsibility" of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700].

If a licensed pharmacist is not on duty, the pharmacy is required to post a sign on the prescription counter and on all entrance doors informing the public that "no pharmacist is on duty." To ensure visibility, sign lettering may be no smaller than two inches (2") in height. [20 CSR 2220-2.010(1)(A)]. *Note: Licensees are not required to post a "no pharmacist on duty sign" if the pharmacist is present in the pharmacy building but momentarily and briefly absent from the pharmacy area.*

C.7 Security

Pharmacies must maintain adequate security to deter theft of drugs by personnel or the public. [20 CSR 2220-2.010(1)(H)]. If the pharmacy is located in a facility that has public access after the pharmacy's normal hours of operation, the pharmacy must have sufficient alarm systems or locking mechanisms to deter theft. Locking mechanisms/alarms, should be able to detect and prevent unauthorized access into the pharmacy (i.e.- access via the ceiling or above gates/doors). Licensees should also consider counter heights, wall/ceiling barriers and ease of public access to the pharmacy. *Note: Licensees must also comply with all controlled substance security requirements.*

The Board has received reports of losses/theft by non-pharmacy staff allowed to access the pharmacy for legitimate business purposes (i.e.- auditing, maintenance). Licensees should ensure the pharmacy is adequately supervised and secured at all times.

C.8 License Posting

The pharmacy's permit and the licenses/registrations of all pharmacists and technicians working in the pharmacy must be conspicuously displayed in the pharmacy area. [20 CSR 2220-2.010(1)(K)]. Pharmacist licenses must be accompanied by a 2"x 2" photo. In lieu of posting, licensees working as relief pharmacists at more than one pharmacy must have proof of licensure in their possession (i.e.- license wallet cards). [20 CSR 2220-2.010(1)(L)].

Pharmacies are also required to maintain a list of all pharmacy technicians authorized to access the pharmacy and their duties, as well as a policy and procedures manual for technician supervision. [20 CSR 2220-2.090(2)(BB), (CC)]. *See sample technician list in the Board's Inspection handout at http://pr.mo.gov/boards/pharmacy/Inspection%20Handout.pdf.*

C.9 Warehouse/Storage Sites

Any site/facility used to store pharmaceuticals or confidential pharmacy records at an address or premises that is separate from the main pharmacy must be registered with the Board. [20 CSR 2220-2.010(1)(I), (J)]. Notification must be made in writing and include:

- The pharmacy's name and permit number;
- The name, address and hours of operation for the off-site location; and
- A statement that the off-site location meets the requirements of 20 CSR 2220-2.010.

Off site storage locations must meet the following requirements:

- Adequate security must be maintained to protect record confidentiality and prevent unauthorized access. At a minimum, the off-site location must be equipped with an alarm system.
- Security breaches must be reported to the Board within 15 days.

- No record less than two years old may be stored off site; and
- All records stored off site must be made available for inspection within two business days, if requested.

Pharmacies may share storage space at the same location if the pharmacy's records and/or pharmaceuticals can be individually identified and are securely stored in a manner that will prevent unauthorized access. However, prescription records must be confidentially maintained at all times, as required by state/federal law.

> *Storing records at another pharmacy is considered offsite storage and requires notification to the Board. Pharmacy records may only be stored off-site if the pharmacy has notified the Board.*

C.10 Staffing Ratios

Missouri does not require or impose mandatory staffing ratios (i.e. pharmacist-to-technician). However, the Board is concerned about the quality of services and the potential for increased dispensing errors if staffing levels are inadequate to ensure appropriate pharmacist oversight. The pharmacist's ability to counsel patients may also be compromised. Licensees are strongly cautioned to maintain professional and appropriate staffing levels to ensure proper supervision.

C.11 Change Of Ownership

Pharmacy permits are not transferable. The Board may issue a temporary pharmacy permit on a change of ownership if a complete permit application has been filed. Accordingly, a permit becomes void on the effective date of an ownership change and a new pharmacy permit is required for the new ownership. [20 CSR 2220-2.020(3)].

- *Sole Proprietors:* A pharmacy owned by a sole proprietorship will be deemed to have changed ownership if: 1) the proprietor enters into a partnership with another individual or business entity, or 2) the proprietor dies. [20 CSR 2220-2.020(3)].
- *Corporations, LLCs, LLPs:* A new pharmacy permit is required if a corporation, limited liability partnership ("LLP"), or limited liability company ("LLC") begins or transfers ownership of a pharmacy. A new permit is required regardless of the relationship between the previous and subsequent owners. However, a change of ownership application is not required if:
    1) The pharmacy is owned by a corporation and the owners of stock change. However, individuals/entities must notify the Board n writing within thirty (30) days of acquiring more than twenty-five percent (25%) of a pharmacy's ownership, or;
    2) The members or partners of a LLP or LLC change, as long as the partnership or company is not dissolved by the change. The pharmacy must notify the Board of any changes in partners/members within ten (10) days after a change occurs. Notification must be certified in writing. [20 CSR 2220-2.020(3)].

> *Licenses should check with BNDD and the DEA to determine how ownership changes may affect the pharmacy's controlled substance registration. A new or amended controlled substance registration may be required.*

C.12 Change Of Location/Remodeling

Pharmacy permits are only valid for the address/structure identified on the permit. A Location Change application must be filed with the Board before the pharmacy moves to a new location. [20 CSR 2220-2.020(4)]. The application must be approved and the premises must be inspected prior to operation. If approved, the Board will issue a permit for the new location with the previous permit number. *Note: Permitholders should notify the Board in writing if the pharmacy's address changes but not the location. An amended permit will be issued without charge.*

Pharmacy Remodeling: A Location Change application is not required for remodeling within an existing structure. However, permitholders must file an affidavit that includes a description of the proposed changes and the projected completion date. [20 CSR 2220-2.020(4)(A)]. The remodeling affidavit and project plans must be filed with the Board no later than thirty (30) days before the changes begin. Rule 20 CSR 2220-2.020(4)(A) defines remodeling as: 1) any change in the storage conditions of Schedule II substances, 2) any new connections to water/sewer resources or 3) any changes in the overall physical security of drugs stored in the pharmacy.

> *A move outside the existing building to a temporary structure during a facility renovation is considered a change of location. A move back to the renovated area is considered a second change of location. Both moves require a separate Location Change application.*
>
> *Licenses should check with BNDD and the DEA to determine how location changes may affect the pharmacy's controlled substance registration. A new or amended controlled substance registration may be required.*

C.13 Non-Resident Pharmacies

Pursuant to 20 CSR 2220-2.025, pharmacies located outside of Missouri may not ship, mail or deliver prescription drugs into Missouri without first obtaining a Missouri pharmacy permit.

To be eligible for licensure, a non-resident pharmacy must be located in the United States or a U.S. territory and maintain a current and active pharmacy license in the state/territory where the non-resident pharmacy is physically located. [20 CSR 2220-2.025]. Non-resident pharmacies must designate a pharmacist-in-charge who will be personally responsible for supervising the pharmacy and who holds an active pharmacist license in the non-resident pharmacy's licensing state/territory. *For non-resident licensure exemptions see 20 CSR 2220-2.025(1).*

C.14 Termination Of Business

Prior to terminating business, the PIC and the permitholder should ensure proper arrangements have been made for all drugs, devices and pharmacy records. An Out-of-Business Notification Form must be filed with the Board within fifteen (15) days after the pharmacy's termination of business date. As

provided in 20 CSR 2220-2.015(5), the pharmacy's termination date is the date the permitholder ceases to practice pharmacy at the permit location. [20 CSR 2220-2.015(1)]. Upon termination, the pharmacy's permit must be returned to the Board with the Out-of-Business form.

The closing pharmacy may transfer or dispose of drugs in accordance with state or federal law. [20 CSR 2220-2.015(2)]. A drug distributor license is not required for a one (1) time transfer of drugs/devices for the pharmacy terminating business. [20 CSR 2220-2.015(3)]. Pharmacies may not transfer misbranded, outdated or adulterated drugs, except for proper disposal. *Licensees should contact BNDD for guidance on controlled substances.*

A complete inventory of all controlled substances transferred or disposed of must be completed on the termination date. [20 CSR 2220-2.015(2)(A)]. If controlled substances are transferred to another licensed entity, the inventory will serve as the final inventory for the terminating pharmacy and the initial inventory for the receiving entity. A copy of the inventory must be included in the records of each licensee or permitholder involved in the transfer.

The closing pharmacy must designate a secure location where pharmacy records will be maintained after closing. Records transferred to an unlicensed location must be retrievable within seven (7) working days of a request by the Board. [20 CSR 2220-2.015(1)(C)].

> *To assist consumers, the Board recommends notifying patients of a pharmacy's closing in advance. The Board also recommends providing customers with contact information for locating/accessing prescription records after closing.*

C.15 Non-Dispensing Activities

Generally, the practice of pharmacy may only be performed on the premises of a Missouri-licensed pharmacy. [20 CSR 2220-6.055]. However, 20 CSR 2220-6.055 allows a Missouri-licensed pharmacist to perform the following non-dispensing activities outside of a licensed pharmacy:

1) *Patient counseling/education, as authorized by Missouri law*
2) *Obtaining patient history/information*
3) *Reviewing patient records/medical histories*
4) *Patient assessment/evaluation, as authorized by Missouri law*
5) *Billing and insurance claim submissions/ review*
6) *Drug utilization review*
7) *Assessing health plan and medication eligibility/coverage*
8) *Pharmacy compliance audits/evaluations*
9) *Administering drugs, vaccines, or biologicals, as authorized by law and the rules of the Board*
10) *Peer review/peer consultations*
11) *Reviewing, selecting, and developing formularies or plan/practice guidelines*
12) *Reviewing compliance with benefit guidelines*
13) *Managing inventory, including purchasing and ordering*
14) *Managing/reviewing information systems*
15) *Patient medication review*
16) *Consulting with other health care professionals*
17) *Patient referrals*
18) *Medication therapy management, as authorized by the rules of the Board*
19) *Prescription order entry/review, provided that a pharmacist may only accept a prescription on the premises of*

a Missouri licensed pharmacy

Pharmacists performing non-dispensing functions under 20 CSR 2220-6.055 may not meet with patients in the pharmacist's residence or living quarters.

> *A pharmacy permit is required if a pharmacy technician will be assisting with the non-dispensing activities listed above (this does not apply to sites used solely for immunization). Technicians may only work under the direct supervision of a pharmacist as required by Missouri law.*

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SECTION D: PRESCRIPTION REQUIREMENTS

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D.1 General Prescription Requirements

Except as otherwise provided by state or federal law, licensees may only dispense medication pursuant to a "prescription" or "prescription drug order" from an authorized prescriber for a specific patient. [§ 338.095]. For purposes of Chapter 338, RSMo, and the Board's rules, a "prescription" or "prescription drug order" is defined as:

> *A lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. The terms "prescription" and "drug order" do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient.* [§ 338.095].

To be valid for dispensing, a "prescription" or "prescription drug order" must:

- Comply with the required prescription format;
- Be issued by an authorized prescriber based on a valid pre-existing patient-practitioner relationship; and
- Contain all information required by state/federal law.

D.2 Prescription Forms

Pursuant to § 338.056, written prescriptions must be on forms with two signature lines on opposite ends of the bottom of the form. The words "dispense as written" must be printed under the signature line on the right and the words "substitution permitted" must be printed under the signature line on the left. [§ 338.056]. A prescriber note indicating "DAW," "brand necessary" or "brand medically necessary" is not sufficient.

Prescriptions from non-Missouri prescribers must be in the format approved by § 338.056 or the form approved in the state/territory where the practitioner is licensed.

> *Faxed prescriptions must be in the required two-line format (See also D.8). Electronically transmitted prescriptions do not have to be in two-line format but must indicate the prescriber's intention on generic substitution. (See also D.10).*

D.3 Authorized Prescribers

To be valid for dispensing, a prescription must have been written by a prescriber that is licensed in the United States or a U.S. territory who is legally authorized to prescribe. [§ 338.095; 20 CSR 2220-2.020(11)]. Missouri law recognizes the following authorized prescribers:

- *Physicians, Dentists, Veterinarians, Podiatrists and Optometrists:* These practitioners may prescribe in the course of their professional practice but may not prescribe outside of their normal expertise or area of licensure (i.e., a dentist or optometrist prescribing amphetamines).
- *Advanced Practice Nurses:* Pursuant to Chapter 335, RSMo, an Advanced Practice Nurse ("APRN") is authorized to prescribe if the APRN has a collaborative practice agreement with a Missouri-licensed physician. Both the APRN and the supervising physician's name must be on the prescription. However, only the APRN is required to sign. *See additional information below on APRN controlled substance authority.*
- *Physician Assistants:* Pursuant to § 334.735, a physician assistant (PA) may issue prescriptions pursuant to a supervisory agreement with a physician. Prescribed medication must be consistent with the PA's scope of practice. Both the PA and the supervising physician's name must be on the prescription per § 334.735.4, RSMo. However, only the PA is required to sign. *See additional information below on PA controlled substance authority.*
- *Non-U.S. Prescribers:* Pharmacists may not fill a prescription from a practitioner licensed in a foreign country/jurisdiction unless the practitioner is also licensed in a state or territory of the U.S. and is legally authorized to prescribe in that state/territory. [§ 338.095; 20 CSR 2220-2.020(11)].
- *Deceased Practitioners:* Missouri law does not definitively address the filling/refilling of prescriptions that were validly written before a prescriber passes away. Pharmacists should use their professional judgment in continuing to dispense refills from a deceased prescriber until the patient can get re-established with a new provider. Patients should be advised to consult with another practitioner as soon as possible. Licensees should contact BNDD for guidance on dispensing controlled substances.
- *Retired Practitioners:* Missouri law does not definitively address the filling/refilling of prescriptions that were validly written before the prescriber retired. Pharmacists should use their professional judgment in continuing to dispense refills. Patients should be advised to consult with another practitioner as soon as possible. Contact BNDD for guidance on dispensing controlled substances.
- *Prescriptions From Other States/Territories:* Other states/territories have enacted broader prescriptive authority for certain practitioners. A pharmacist may fill a prescription from a non-Missouri prescriber if the prescriber is legally authorized to issue the prescription in the state/territory where the prescriber is licensed. The prescription may be filled even if similar prescriptive authority is not recognized/granted in Missouri. (i.e.- out-of-state chiropractors, pharmacists or psychologists with prescriptive authority).

  According to BNDD, out-of-state prescribers may prescribe controlled substances according to the authority of their home state. If the patient is a Missouri patient, Missouri's quantity limits apply as listed in § 195.080. If the patient is an out-of-state patient, the quantity limits of that home state apply.

Licensees are responsible for ensuring valid prescriptive authority (controlled substance prescribers must also have any required BNDD/DEA registrations). The DEA publishes a state listing of controlled substance prescribers at http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. The National Association of Boards of Pharmacy (NABP) also publishes a state-specific listing in its annual Survey of Law that can be purchased/downloaded at http://www.nabp.net/publications/survey-of-pharmacy-law/. These resources are not maintained by the Board. Accordingly, the Board cannot guarantee their accuracy. Licensees are encouraged to contact the applicable state to ensure prescriptive authority.

******Additional Information for Advanced Practice Registered Nurses and Physician Assistants******

BNDD is now issuing controlled substance registrations to advanced practice registered nurses (APRNs) and physician assistants (mid-level practitioners). As of December 1, 2011, these mid-level practitioners are authorized to prescribe controlled substances, as authorized by Missouri law. To assist in compliance, BNDD has issued the following general guidance:

- Mid-level practitioners must be in a collaborative or supervision agreement with a physician who also has a current BNDD and DEA registration. Mid-level practitioners may not purchase, stock, dispense, or administer controlled substances independently.
- Mid-level practitioners may prescribe controlled drugs in Schedules III, IV, and V only. There is no authority for Schedule II drugs.
- Like other prescribers, mid-level practitioners may not prescribe, administer or dispense controlled drugs to themselves.
- Mid-level practitioners may not prescribe controlled drugs to family members. "Family" is defined in the state medical board's rule 20 CSR 2150-5.100(3)(G)(10) as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law or son-in-law. Adopted and step members are also included in the definition of "family."
- ***Out-of-State Practitioners***: Pursuant to Section 195.060.1, RSMo, Missouri pharmacies may in good faith dispense controlled drug prescriptions from out-of-state practitioners, as long as the prescriptions were written in compliance with the laws of the applicable state.

- **Difference in Schedule III Prescribing Quantities:**
  - ***APRNs***: When prescribing a Schedule III **opiate/narcotic**, APRNs are limited to a 120-hour (5-day) supply with no refills on the prescription. Section 334.104.2, RSMo gives APRNs normal prescribing authority for non-opiate/narcotic Schedule III drugs.
  - ***Physician Assistants***: Physician assistants are limited to a 120-hour (5-day) supply for **all** Schedule III drugs, with no refill. These practitioners may, however, issue an entirely new prescription after 5 days that would generate a new prescription and new prescription number. According to BNDD, these would be considered new prescriptions and not refills.
- **Change in Labeling Requirements**: Section 195.100, RSMo, contains amended labeling requirements for controlled drug prescriptions issued by mid-level practitioners. Generally, the prescription label must document both the names of the prescribing mid-level practitioner and their supervising or collaborating physician per the Board of Nursing's rules. If the physician's name is not

provided, the pharmacy must call the prescriber and document the name. *Note: This pertains to "prescriptions" and not to internal drug "orders" for in-patients of a licensed hospital.*

The revised statutory requirements can be found in § 334.104 (APRNs) and § 334.747, RSMo (physicians' assistants). Additional compliance information can be found on BNDD's website at http://health.mo.gov/safety/bndd/index.php.

D.4 Valid Patient-Practitioner Relationship

Prescriptions must be based on a valid pre-existing patient-practitioner relationship. [20 CSR 2220-2.020(11)]. Additionally, the practitioner must have "performed a sufficient physical examination and clinical assessment of the patient." [20 CSR 2220-2.020(11)]. If the pharmacist knows or has reason to believe the patient is not under the prescriber's care at the time the prescription is presented for filling/refilling, the pharmacist is required to consult with the prescriber to ascertain if the prescriber intends for the medication to be dispensed. The prescription must be confirmed even if additional refills have been authorized. Confirmation should be documented in the prescription record. *However, see D.3 for retired prescribers.*

A prescription may not be filled if the pharmacist knows, or should reasonably know under the circumstances, that the prescription was based on an internet-based questionnaire, an internet-based consultation or a telephone consultation. [20 CSR 2220-2.020(11)].

> *It is illegal for a physician to prescribe controlled substances for him/herself, unless it is a medical emergency (see § 195.070.4, RSMo). It is not illegal for a physician to prescribe non-controlled drugs for him/herself, however, the practice is discouraged by the Board of Healing Arts. Physicians may prescribe controlled or non-controlled drugs for a family member, as long as the physician maintains the same records for family members as he/she would for any other patient and all other prescription requirements are met.*

D.5 Prescription Requirements

(The information below is required for all manual, telephone, verbal and electronic prescriptions)

Pursuant to 20 CSR 2220-2.018, a prescription must include:

1. The prescription date and a unique, readily retrievable identifier;
2. The name of the patient(s);
3. The prescriber's name for oral prescriptions and signature for written prescriptions;
4. Any prescriber indication of name, dosage of drug and directions for use;

The name and dosage of the drug dispensed;

5. The number of refills, if applicable;
6. The quantity dispensed in weight, volume or number of units;
7. The initials or name of the pharmacist responsible for dispensing or compounding the prescription; and
8. Any change or alteration made to the prescription dispensed based on contact with the prescriber. This includes, but is not limited to, any change in quantity, directions, refills or substitution authorization.

Controlled substance prescriptions must also include:

1. The address of the prescriber and the patient; and
2. The prescriber's Drug Enforcement Administration (DEA) number.

Changes in prescription orders may only be communicated by the prescriber or a duly authorized representative. Pharmacists may not rely on notifications that are transferred or communicated by an unlicensed third party. (i.e.- an insurer/pharmacy benefit manager). For authorized changes to C-II prescriptions, see BNDD's Interim Schedule II Policy.

> *The Board does not have jurisdiction over pharmacy practice on military bases. Prescriptions from a member of the armed forces may be filled by a Missouri pharmacy if the prescription complies with all requirements of federal law.*
>
> *See Section E.5 for additional information on dispensing epinephrine or asthma related medications for school districts.*

D.6 Authorized Signatures

- ***Non-Controlled Substances:*** Non-controlled prescriptions may either be manually or electronically signed by the prescriber. [§ 338.056].
  - *Manual Signatures:* Prescribers may manually sign a prescription in the same manner used for signing a check or other legal document. Rubber-stamped signatures are not valid for dispensing. The prescriber's staff/agents may prepare the prescription. However, the prescriber must manually sign the prescription before issuance.
  - *Electronic Signatures:* A prescription may be electronically signed if: a) the prescription has been applied to secure paper that prevents/detects copying or alteration or b) the prescription is faxed to the pharmacy from the prescriber's office or the prescriber's authorized agent. [20 CSR 2220-2.085(2)(D), (E)]. To be valid, the electronic signature must be an exact electronic replica of the prescriber's signature or consist of a confidential digital key code, number or other identifier that denotes prescriber authorization (i.e.- the Board has allowed phrases such as "electronically prescribed by John Smith, MD") [20 CSR 2220-2.085(1)(D)]. [*See also D.8- Faxed Prescriptions / D.10- Electronic Transmissions*].

Licensees may contact the prescriber to obtain an oral prescription if a signature is invalid.

- ***Controlled Substances:*** Controlled substance prescriptions must be signed as required by state or federal law. Generally, all paper prescriptions and faxed prescriptions must be manually signed by the prescriber. According to BNDD, digitally scanned signatures are not acceptable. With the exception of Schedule II controlled substances, licensees may obtain an oral prescription if the prescriber's signature is invalid.

The DEA has promulgated rules which authorize the electronic transmission and electronic signature of controlled substance prescriptions if the pharmacy and prescriber are using software that has been

certified to meet DEA requirements. (See also Section D.10). Electronic controlled substance prescriptions must comply with all applicable federal law.

D.7 Telephone Prescriptions

Pharmacists may accept a telephone prescription communicated by the prescriber or the prescriber's duly authorized agent. [§ 338.095]. Section 338.095 defines a "*telephone prescription*" as:

> *An order for medications or devices transmitted to a pharmacist by telephone or similar electronic medium by an authorized prescriber or his authorized agent acting in the course of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user.*

Telephone prescriptions must be promptly reduced to writing or electronically recorded in the pharmacy's prescription records. All prescription information required by 20 CSR 2220-2.018 must be recorded, including, an indication of whether the prescriber has authorized generic substitution. Telephone information may be received by a pharmacist or by a technician/intern pharmacist acting under the pharmacist's direct supervision.

D.8 Faxed Prescriptions

Faxed prescriptions must be in the required two-line format and include all prescription information required by § 338.056 and 20 CSR 2220-2.018. Faxed prescriptions for non-controlled substances may be manually signed or electronically signed as authorized by 20 CSR 2220-2.085. To be valid, the electronic signature must be an exact electronic replica of the prescriber's signature or consist of a confidential digital key code, number or other identifier that denotes prescriber authorization (the Board has allowed phrases such as "electronically prescribed by John Smith, MD") [20 CSR 2220-2.085(1)(D)]. The original fax must be readily retrievable from the pharmacy's electronic or hard copy files. [20 CSR 2220-2.085(2)(A)].

A true faxed prescription is a full image of a physical prescription document that is faxed to the pharmacy. [20 CSR 2220-2.085(1)(B)]. In other words, the sender must insert a fully completed prescription document into the fax machine and fax the prescription to the pharmacy. Faxed prescriptions may only be sent by the prescriber or the prescriber's authorized agent. Pharmacies are not allowed to fill prescriptions faxed by a patient.

> *Non-controlled prescriptions sent from a prescriber's computer to the pharmacy's fax machine are electronically transmitted prescriptions and are not considered "faxed prescriptions".*
>
> *Faxed controlled substance prescriptions must be physically signed by the prescriber and must comply with all BNDD and DEA requirements. The DEA does not allow an **electronically signed** controlled substance prescription that is generated from a prescriber's software to be converted to fax. See 20 CSR 2220-2.085 and Section D.10 for electronically transmitted prescription requirements.*

D.9 Prescription Limits

Missouri law imposes the following prescription limits:

REQUIREMENTS FOR MISSOURI PHYSICIANS

	Schedule II Controlled Substances	Schedule III-IV Controlled Substances	Schedule V Controlled Substances	Non-Controlled Substances
Prescription Validity	Six (6) Months	Six (6) Months	One Year	One Year
Quantity Limits	30-Days/ 90-Days with documented medical reason	90-Days	90-Days	As prescribed
Refills	May not be refilled	Up to five (5) times within six (6) months	As prescribed	As prescribed

BNDD has determined these controlled substance limits/restrictions apply to prescriptions written by Missouri physicians for both Missouri and non-Missouri patients.

CONTROLLED SUBSTANCE LIMITS FOR MISSOURI ADVANCED PRACTICE REGISTERED NURSES & PHYSICIAN ASSISTANTS

	MISSOURI APRN	MISSOURI PHYSICIAN ASSISTANT
AUTHORITY	May prescribe Schedules III – V. CANNOT prescribe Schedule II.	May prescribe Schedules III – V. CANNOT prescribe Schedule II.
PRESCRIPTION VALIDITY	Six (6) months from date signed	Six (6) months from date signed
QUANTITY LIMITS	• Schedule III opiates limited to a 5-day or 120 hour supply. • Non-opiate Schedule III and all of Schedule IV & V limited to a 90-day supply.	• All Schedule III drugs limited to a 5-day or 120 hour supply. • Schedules IV & V limited to a 90-day supply.
REFILLS	• Schedule III opiates no refills • Non-opiate Schedule III and all Schedules IV & V limited to five (5) refills.	• Schedule III no refills • Schedules IV & V limited to five (5) refills.

**Limits for APRN & PA non-controlled prescriptions are the same as physicians (see above).*

BNDD has determined Missouri's mid-level practitioner Schedule II prohibition and Schedule III quantity limits do not apply to prescriptions from out-of-state mid-level practitioners for both Missouri and non-Missouri patients. However, the prescriber must apply with the quantity limits of their home state.

D.10 Electronic Transmissions

Non-Controlled Substance Prescriptions: Prescriptions for non-controlled drugs may be transmitted electronically as an "electronic image transmission" or an "electronic data transmission", which are defined in rule 20 CSR 2220-2.085(1) as:

- *Electronic data transmission prescription*": A prescription order, other than an electronic image transmission, that is electronically transmitted from the licensed prescriber to the pharmacy. [20 CSR 2220-2.085(1)(B)].
- *"Electronic image transmission prescription":* An exact visual image of a prescription order that is received by a pharmacy from a licensed prescriber. To be an electronic image transmission, the prescriber must have a physical document. Faxed prescriptions constitute an electronic image transmission if a full image of the physical prescription is faxed to the pharmacy (i.e.- sender inserts a fully completed prescription into the fax machine). *[See Section D-8 for additional fax requirements]*.

Prior to dispensing, pharmacists should take appropriate measures to verify/authenticate electronic prescriptions and their source of origin. [20 CSR 2220-2.085(2)(C)]. Licensees should use their professional judgment in determining appropriate verification/authentication measures. Appropriate measures may include:

- Maintaining a practitioner fax number reference list or other electronic signature file;
- Verification of the telephone/fax number; and
- Orally verifying with the prescriber's office that the prescription is correct as written and as transmitted. [20 CSR 2220-2.085(2)(C)].

The original fax and any other information sent from the electronic source must be readily retrievable from the pharmacy's electronic or hard copy files. [20 CSR 2220-2.085(2)(A)]. Any alteration(s) to the prescription after dispensing must be documented in the prescription records along with the identity of the pharmacist responsible for the alteration. [20 CSR 2220-2.085(2)(A)].

Controlled Substance Prescriptions: The DEA has promulgated rules which authorize the electronic transmission and electronic signature of controlled substance prescriptions if the pharmacy and prescriber are using software that has been certified to meet DEA requirements. Electronic controlled substance prescriptions must comply with all state and federal requirements.

D.11 Prescription Refills (Original & Transfers)

Note: This section applies to both original prescription transfers and refill transfers

Upon request, a prescription MUST be transferred if: 1) the prescription is still valid and has authorized refills and 2) the number of lawfully allowable refills has not been reached. [20 CSR 2220-2.120]. Transfer may be requested by the patient or from another pharmacy at the patient's request. Transfer is mandatory and must be completed within one (1) business day of the patient's request. [20 CSR 2220-2.120(3)].

The Board is aware of pharmacies improperly denying transfers due to patient-pharmacy disputes, pharmacy-pharmacy disputes, unpaid patient accounts/bills, or refills being too soon. If the refill

appears to be too soon, the transferring pharmacy may call attention to the early refill but **cannot** deny the request. The receiving pharmacy is responsible for reviewing the prescription before dispensing, including determining if the refill is too soon.

Prescriptions may only be transferred to a Missouri-licensed pharmacy or a pharmacy licensed in another U.S. state/territory. [20 CSR 2220-2.120(1)]. Prescriptions may not be transferred to an unlicensed entity or a foreign pharmacy (i.e.- a pharmacy not located in a U.S. state/territory).

The transferring and receiving pharmacy must record the following information:

TRANSFERRING PHARMACY	RECEIVING PHARMACY
✓ The name of the pharmacy receiving the transfer; ✓ The transfer date; ✓ The identity of the transferring pharmacist (*Unless otherwise required by federal law, the transferring pharmacist's identity is not required for electronically transferred prescriptions*); and ✓ The prescription must be immediately voided in the pharmacy's electronic system or the word "void" must be written on the face of the invalidated prescription. ✓ If the transfer involves a controlled substance, the address and DEA registration number of the receiving pharmacy.	✓ All information required for an original prescription; ✓ An indication/notation that the prescription was transferred from another licensed location; ✓ The date the prescription was originally issued; ✓ The date of original filling, if different from the original issuance date; ✓ The number of refills authorized on the original prescription and the number of remaining authorized refills;* ✓ The date of the last refill;***** ✓ The prescription label number;***** ✓ The identity of the licensed pharmacy that transferred the prescription; ✓ The transferring pharmacist, and; ✓ If the transfer involves a controlled substance, the address and DEA registration number of the transferring pharmacy. **** Not required for original prescription refills.***

Electronic transfers are allowed if the pharmacies are under the same ownership and share the same database. The prescription may be transferred by generating a computer-based report at the transferring pharmacy of all prescriptions transferred out. [20 CSR 2220-2.120(2)(B)8.]. The transfer record must be readily retrievable by the transferring pharmacy and must include all information required by 20 CSR 2220-2.120.

Pursuant to 20 CSR 2220-2.140(5)(D), if a pharmacy is dispensing to a long-term care facility pursuant to a nursing home order, refills associated with the order are not valid for transfer.

Controlled Substances: The following general requirements apply to controlled substance transfers:

- Schedule II controlled substances may not be transferred. [20 CSR 2220-2.120(1)(B)].
- Schedule III-IV controlled substances may be transferred, however, transfer information may only be communicated between licensed pharmacists. [20 CSR 2220-2.120(1)(D)]. Pharmacy technicians or intern pharmacists may not provide or receive controlled substance transfers.
- Schedule III – V controlled substance prescriptions may only be transferred once. [20 CSR 2220-2.120(1)(E)]. However, additional transfers are allowed if the pharmacies electronically share a real-time, online database. [20 CSR 2220-2.120(1)(E)].

> *Pharmacies electronically transferring controlled substance refills using electronic means need to be aware that 20 CSR 2220-2.120 and Drug Enforcement Administration (DEA) regulation 21 CFR 1605.25 require that all information for controlled substance refills must be transferred directly between two pharmacists. The transfer of controlled substances refills without the direct involvement of two pharmacists is prohibited- even if the pharmacies share a common database or have a Class J Shared Services arrangement.*
>
> *DEA reiterated their position in the following response to comments to the Electronic Prescriptions for Controlled Substances regulation published in the March 31, 2010 Federal Register, page 16268:*
>
> > *DEA has never permitted the transfer of a controlled substance prescription without the involvement of two licensed pharmacists, regardless of whether the two pharmacies share a common database.*
>
> *Licensees should review their transfer procedures to ensure compliance with state and federal controlled substance law.*

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SECTION E: PRESCRIPTION DISPENSING

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E.1 General Requirements

Licensees may lawfully dispense medication pursuant to a valid prescription from an authorized prescriber. Registered/licensed pharmacy staff may assist in preparation, however, all activities must be supervised by a Missouri-licensed pharmacist. [20 CSR 2220-2.010(1)(B)]. Prior to dispensing, a Missouri-licensed pharmacist must inspect and verify the prescription's accuracy, including, the contents and the affixed label. [20 CSR 2220-2.010(1)(B)].

Licensees may only dispense medication received from a Missouri-licensed drug distributor or transferred from a Missouri-licensed pharmacy by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form (schedule II drugs). *(See also rule 20 CSR 2220-2.650 for Class-J Shared Services transfers).* Unless otherwise allowed by federal law, drug samples may not be dispensed by, or maintained in, the pharmacy. [20 CSR 2220-2.010(8)].

> *Dispensing errors increase the risk of unnecessary medical consequences and threaten the public's safety. Licensees should take proactive steps to prevent and detect errors. The Board encourages licensees to voluntarily report dispensing errors to the USP-ISMP Medication Errors Reporting Program. This confidential program gathers and analyzes data to help prevent future errors. Reports may be submitted online at www.ismp.org.*

E.2 Labeling

A written label must be affixed to every prescription container dispensed to a consumer indicating:

1) The date the prescription was filled;
2) A sequential prescription number;
3) The patient's name;
4) The prescriber's directions for usage;
5) The prescriber's name;
6) The pharmacy's name and address;
7) The exact name and dosage of the drug dispensed, and;
8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy's records by name or abbreviation. [§ 338.059].

Missouri law does not prohibit the addition of other label information. However, prescription labels should be clear and easily readable.

E.3 Patient Counseling

Patients must be offered the opportunity to consult with a Missouri-licensed pharmacist each time a prescription is dispensed (new or refill). [20 CSR 2220-2.190]. The offer to counsel may be extended by pharmacy staff. However, counseling may only be provided by a Missouri-licensed pharmacist or

a Missouri-licensed intern pharmacist acting under the pharmacist's immediate supervision. [20 CSR 2220-2.190].

If the patient or caregiver is not available, a written offer to counsel must be provided with the patient's medication along with a toll-free telephone number for the dispensing pharmacy. [20 CSR 2220-2.190(1)].

Patient counseling is not required:

- For inpatients of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications, or;
- If the patient or caregiver refuses consultation. [20 CSR 2220-2.190(4), (5)].

Counseling should focus on enhancing or optimizing drug therapy and promoting safe/appropriate medication use. [20 CSR 2220-2.190(1)]. Supplemental information may be provided if appropriate (i.e.- leaflets, pictogram labels, video programs, etc.). [20 CSR 2220-2.190(3)]. At a minimum, pharmacists must provide any counseling required by state/federal law.

To facilitate counseling, licensees are required to collect and maintain appropriate patient information. Appropriate information may include, but is not limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a list of other drugs prescribed. [20 CSR 2220-2.190(2)].

E.4 Generic Substitution [§ 338.056]

Unless otherwise requested by the patient, a pharmacist may substitute a generic equivalent if:

- The drug substituted is not listed as therapeutically inequivalent to the product prescribed in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book);
- The generic substitution costs less than the prescribed product; and
- The prescriber authorized substitution. Authorization may be provided orally, electronically (for electronic prescriptions) or by signing the "Substitution Permitted" line on the prescription. [§ 338.056]. If the prescription was issued by a non-Missouri prescriber, substitution is authorized if allowed by the prescriber's licensing state/territory. The required prescription format is dictated by the laws of the prescriber's home state (i.e.- two-line, one-line, checkbox, etc.).

If a generic product is substituted, the manufacturer's name or abbreviation must be identified on the prescription label or in the pharmacy's records.

> *Printing only a brand name when a generic product is dispensed is misleading to the public and considered misbranding. Some licensees list the generic product on the label and then use the statement "substituted for" with the brand name of the product that is being substituted. This is acceptable if the label is not misleading. However, there is no law requiring that a brand name be used on a label when substitution takes place.*

E.5 Dispensing For Office Stock

To be valid for dispensing, a prescription must be written by an authorized prescriber for a specific patient. [§ 338.095]. Licensees are NOT allowed to dispense drug products for office stock by prescription. Licensees may, however, dispense medication pursuant to a patient-specific prescription to be administered by the prescriber to an individual patient.

Alternatively, pharmacies may transfer medication by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form (Schedule II drugs). [See E.14 for additional information on drug transfers]. Pharmacies may not repackage drugs for distribution to other practitioners without being registered with the FDA as a repackager.

Epinephrine & Asthma Related Medication for School Districts

Section 167.630, RSMo, authorizes Missouri school districts to obtain prefilled epinephrine auto syringes by prescription. Section 167.635 contains the same allowance for asthma related medications. To obtain prefilled epinephrine syringes or asthma related medications, a prescription is required from a licensed physician, a physician's assistant, or nurse practitioner. The school district must be designated as the patient and the school nurse's name must be on the prescription. Pharmacies may legally dispense pursuant to a prescription that complies with § 167.630 or § 167.635.

E.6 Prescription Delivery Sites

Pursuant to 20 CSR 2220-2.013, prescriptions filled by a Missouri pharmacy "may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy." However, filled prescriptions may be delivered to the following location at the request of the patient or the patient's authorized designee:

- The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;
- A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;
- A hospital, office, clinic or other medical institution that provides health care services;
- A residence designated by the patient or the patient's authorized designee, or
- The patient's office or place of employment.

Prescriptions may be delivered to other non-pharmacy locations not specified in the rule only if the prescription is delivered directly to the patient or the patient's authorized designee. Prescriptions may be delivered to another pharmacy for dispensing if both pharmacies are in compliance with 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy).

Pharmacies delivering medication to a non-pharmacy location as allowed by the rule must develop ***written*** policies and procedures "to ensure the safe and appropriate delivery of prescription drugs within the temperature ranges recommended by the manufacturer or the *United States*

Pharmacopeia." Policies and procedures should be maintained at the pharmacy and accessible for review on request or during an inspection.

Patient authorization to deliver a prescription may be received verbally, electronically or in writing. The Board recommends documenting patient authorization and the requested location in the pharmacy's prescription records.

E.7 Misbranding/Adulteration

State and federal law prohibits dispensing any misbranded or adulterated substance. The Board defines "misbranded" and "adulteration" consistent with state and federal law, including, but not limited to, Sections 501 and 502 of the Food, Drug and Cosmetic Act [21 USC § 351 , § 352], § 196.095 and § 196.100, RSMo.

Outdated, distressed, misbranded or adulterated drugs must be physically separated from the active inventory and maintained in a separate area. [20 CSR 2220-2.090(2)(V)]. Segregated areas must be adequately identified to ensure outdated, distressed, misbranded or adulterated drugs do not re-enter the pharmacy's active inventory.

> ***Reheating/Resealing:*** *The Board has received questions regarding sealing/resealing drugs more than once in the type of packaging where intense heat is utilized to seal the packaging (i.e.- blister cards). Currently, USP does not have a policy regarding this practice. However, USP discourages the practice because the effect of reheating on the medication is unknown. As noted by USP, many manufacturers also recommend against heat sealing drugs more than once. In accordance with USP, the Board discourages the practice.*

E.8 Early Fills/Refills

Board inspectors have observed medications being dispensed too soon to the same patient. In some instances, the "early fills/refills" may result from processing prescriptions from different prescribers or refilling a prescription on a cycle that does not correlate with previously dispensed amounts. Under state and federal law, pharmacists have a professional obligation to ensure drugs are dispensed for bona fide purposes and are not being abused or diverted due to excessive purchases. Licensees should review patient records to ensure compliance with prescribed directions and prevent excessive dispensing.

E.9 Childproof Containers

The Board has signed an agreement with the Consumer Product Safety Commission ("CPSC") to assist in enforcing childproof container laws. All dispensed prescriptions must be packaged in a childproof container. A non-childproof container may be issued if:

- The physician specifically requests that a non-childproof container be dispensed. Pharmacists cannot honor blanket requests from a prescriber to never use safety caps for the prescriber's patients, or;

- The patient specifically requests a non-childproof container. Patients may issue a blanket request for all prescriptions. However, a single request cannot be used as a blanket waiver for subsequent prescriptions. The Board recommends documenting patient requests for non-childproof containers in writing.

The Board is required to report significant violations of the childproof container laws to the CPSC. Under federal law, violations may result in criminal or civil liability. The pharmacy related provisions of the Poison Prevention Packaging Act can be found at 16 CFR 1700.14.

E.10 Tablet Splitting

A number of insurance plans and their agents have begun to require tablet splitting. Generally, pharmacists have been asked to:

- Dispense double the strength of a prescribed drug and then split the tablets in half for the delivery of the original intended dose. After splitting the tablets, the pharmacist makes changes to the directions to coincide with the change in tablet strength, or;
- Supply a drug in whole form and change the label directions to indicate that half of a tablet is to be administered for each dose. Some insurance plans are requiring that tablets with coatings or non-scored tablets be dispensed with the expectation that they be split.

The Board is concerned that these insurance practices may not be in the patient's best interest. As licensed professionals, pharmacists must provide appropriate medications in their proper form. Only drug products that are scored should be used in tablet splitting. This includes splitting tablets into half or quarter tablets. Drugs that are not scored will likely not split in a manner that will provide a uniform dose. Coated tablets may also present problems because once the drug is split, any effect the coating provides may be compromised.

Before tablet splitting, pharmacists should verify that:

1) The literature, or other recognized compendia for the drug, recognizes or indicates that splitting of the specific brand of tablet can be accomplished safely and effectively;
2) The prescriber has approved any change in the prescription if a strength higher than that originally prescribed is used, and;
3) The patient has received detailed patient counseling to ensure the patient understands the changes made to the prescription. If the patient is responsible for splitting the tablet, counseling should be provided on splitting techniques and the use of any related items (i.e.- tablet splitters).

For additional FDA information on patient safety information on tablet splitting, visit http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=54#7 .

E.11 Prepackaging [20 CSR 2220-2.130]

To assist in dispensing, medication may be removed from the original manufacturer's container and placed in a dispensing container where the medication will be stored until dispensed to a patient (i.e.- an automatic dispensing system). Only products that will be directly provided to the patient may be prepackaged.

Proper sanitation procedures must be utilized when repackaged drugs. Drugs should not be handled with bare hands. Additionally, all containers and equipment must be properly cleaned and maintained to prevent contamination. Reusable containers should be kept clean of tablet dust and other contaminants.

At a minimum, containers used for prepackaging must meet USP Class B container standards. Light sensitive containers must be used, if applicable. A label must be affixed to the prepacked drug container indicating the drug's name and strength, the manufacturer/distributor and the required expiration date. The maximum allowed expiration date is twelve (12) months or the manufacturer's expiration date, whichever is less. In lieu of the required label, licensees that store drugs in an automated counting device may record the required lot number/expiration date in the pharmacy's records, provided the information must be fully traceable and readily retrievable during an inspection.

E.12 Patient Med Paks [20 CSR 2220-2.145]

In lieu of dispensing multiple containers, licensees may dispense multiple medications in a single customized patient medication package ("patient med pak"). Patient med paks must comply with rule 20 CSR 2220-2.145. An authorized "patient med pak" is defined as a package prepared for a specific patient that consists of one or more containers which contain two (2) or more prescribed drugs. Patient med paks may only be used for solid oral dosage forms (i.e.- tablets). Med paks may not contain controlled substances.

Prior to dispensing a med pak, pharmacists must consider:

- Any applicable compendia requirements or guidelines;
- The physical and chemical compatibility of the dosage forms placed in each container; and
- Any therapeutic incompatibilities if the medications are administered simultaneously. *The Board encourages licensees to report any observed or reported incompatibilities to USP*.

Containers: Med Pak containers must be non-reclosable or designed to show if the container has been opened. Containers must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container, unless more stringent requirements exist for a drug contained in the med pak. USP has warned about potential physical and/or chemical incompatibilities when certain drugs are packaged together. Pharmacists must ensure that no interactions will occur when preparing multi-med packages.

Labeling: Med paks must be designed or each container labeled to indicate the day and time or period of time that the contents in each container should be taken. Med paks must also bear a label indicating:

1. The patient's name;
2. A serial number for the patient med pak and a separate serial number for each prescription order for each drug contained in the med pak;
3. The name, strength, physical description or identification and total quantity of each drug product;
4. Directions for use and any cautionary statements contained in the prescription order for each drug;

5. Any storage instructions or cautionary statements required by the official compendia;
6. The name of the prescriber for each drug product;
7. The preparation date and beyond-use date assigned. The beyond-use date may be no later than sixty (60) days from the date of preparation;
8. The name, address, and telephone number of the dispenser; and
9. Any other information, statements, or warnings required for any drug included.

If intact containers can be removed or separated from the patient med pak, each individual container must contain a label that identifies all medication in the container.

Package Inserts: Package inserts must be provided if required for any drug in the med-pak. In lieu of an individual insert, the required information may be incorporated into a single, overall insert for the entire med pak.

Records: Records must be maintained for each med pak dispensed. Records must include:

1. The patient's name and address;
2. The prescription serial number for each drug contained in the med pak;
3. The name of the manufacturer/labeler and lot number for each drug;
4. The preparation date and the assigned beyond-use date;
5. Any special labeling instructions;
6. The name or initials of the preparing pharmacist; and
7. Information identifying or describing the design, characteristics, or specifications of the med pak. The med pak must be described in a manner that would allow an identical med pak to be made.

Returns: Generally, med paks that have been delivered to an institution or to a patient cannot be returned to the pharmacy. However, 20 CSR 2220-2.145 provides a pharmacist may modify/repackage a med pak that has been delivered to an institution or patient if:

1. The med pak is returned to the pharmacy that originally dispensed the med pak;
2. The med pak is modified/repackaged, per prescription order, for the same patient to whom it was originally dispensed;
3. The med pak is labeled in compliance with 20 CSR 2220-2.145. The med pak must retain the original beyond use date assigned to the med pak before modification/ repackaging;
4. The med pak is assigned a new serial number, and;
5. The medications removed from the med pak are destroyed in compliance with state and federal law. Removed meds CANNOT be returned to stock/inventory or dispensed to another patient.

Pharmacists modifying/repackaging medication pursuant to 20 CSR 2220-2.145 must comply with all applicable record keeping requirements.

Except as otherwise allowed by 20 CSR 2220-2.145 for modification/repackaging purposes, medication that has been commingled with other drugs in a med pak may not be returned to stock, dispensed, or distributed except for destruction purposes.

> *Compliance with 20 CSR 2220-2.145 is required even if the container is supplied by the patient.*

E.13 Return, Re-Use & Disposal

► ***Return To Stock*** [20 CSR 2220-3.040]**:** A prescription may be returned to stock if: 1) the patient did not receive the prescription and 2) the prescription was maintained in accordance with the manufacturer's labeled storage requirements at all times. The prescription must be maintained in the original patient container with the name of the drug, dispensing date and the prescription number visible on the container. Notations may be made on the label to distinguish it from active prescriptions being processed.

Drugs returned to stock may not be poured back into the original stock container because the drug has undergone manipulation outside of its original container. The mixing of lot numbers is also prohibited. Drugs returned to a stock container will be deemed misbranded and/or adulterated in violation of state and federal law.

If returned to stock, the drug's expiration date must become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known. Prescriptions returned to stock must be deleted from the pharmacy's records and third party payor claims must be reversed (i.e.- insurance).

► ***Returns for Disposal****:* Section 338.315 provides "it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs from anyone other than a licensed or registered drug distributor or pharmacy." Similarly, 20 CSR 2220-3.040 prohibits a pharmacist/pharmacy from accepting any drug or prescribed medicine, device or product for reuse or resale. As a result, a pharmacy cannot accept returns of legend products for disposal from any entity or person, including, the patient. This restriction also applies to patient med paks that have been dispensed to the patient or an institution.

> *Medication Take Back Programs: The Board is aware of alternative drug take-back programs conducted by state and federal law enforcement agencies. Under these programs, drugs are returned to collection sites/receptacles that are under the supervision of law enforcement personnel and located outside of the permitted pharmacy area. The Board considers these programs to be in compliance with Missouri law if the licensee* ***does not take possession*** *of returned medications for purposes of disposal as prohibited by statute. The Board will not consider returned medication to be under the* ***possession*** *of a licensee if: (1) medications are returned to collection sites/receptacles that are outside of the permitted pharmacy area(s), (2) returned medications remain under the control of law enforcement at all times, and (3) law enforcement personnel is present whenever drugs are returned or on site. The Board recognizes the important role take-back programs can play in preventing diversion and eliminating environmental hazards. Resources on safe patient disposal are available on the Board's website. To ensure compliance, licensees should review all applicable state and federal law before participating in a take-back program*

▶ ***Errors:*** As authorized by federal law, the Board has allowed returns to the pharmacy if the wrong medication was dispensed to the patient or in instances of a drug recall. In no instance may returned medication be reused or returned to stock. *[20 CSR 2220-3.040(3)]*.

▶ ***Long-Term Care/Hospice Facilities and Hospitals:*** Licensees may receive and reuse drugs from a long-term care facility, hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services under 19 CSR 30-35.020, if:

1) The medication was originally dispensed by the pharmacist or pharmacy to the institution/facility;
2) The pharmacist has assurance from a person at the institution/facility responsible for the medication that the drugs were stored in accordance with the manufacturer's recommendations and USP standards; and
3) There is an established mechanism to trace the expiration date and the manufacturer's lot number for the returned medication.

Returned drugs from a long-term care facility, hospital or hospice facility may be reused if:

1) The drug products are returned sealed in the original manufacturer's tamper-evident packaging;
2) The drug products were repackaged by a licensed pharmacy or an FDA-registered repackager and are returned sealed in the repackager's tamper-evident packaging, or;
3) The drug products are returned in unit-of-use packaging and the unused portions can be separated and reused without any further repackaging.

Returned medication must be re-labeled to provide accurate patient and prescription information. The original lot numbers, expiration date(s) or beyond-use-date(s) may not be altered.

As used in the Board's rules, a "long-term care facility" is defined as a "nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients." [20 CSR 2220-2.020(9)(C)].

E.14 Distributing vs. Dispensing [§ 338.333, § 338.330]

Pharmacies may transfer legend drugs or drug-related devices to another pharmacy or an authorized prescriber by invoice (schedule III-V drugs/non-controlleds) or via a DEA 222 form (schedule II drugs). Prescriptions cannot be used to transfer drugs to a pharmacy or prescriber.

If medication is transferred by invoice, the pharmacy's invoice record must include:

- Date of distribution;
- Product name/strength;
- Quantity;
- The names of the parties; and
- The transferring pharmacy's full address and DEA #, if a controlled substance.

Licensees are required to retain copies of invoices. Invoices must be maintained separately from the pharmacy's prescription records. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy's total gross drug sales to other pharmacies/prescribers. [§ 338.330(2)].

Controlled substance transfers must comply with federal/state controlled substance laws.

> *Pharmacies that "borrow" or "loan" medication amongst themselves must maintain records of the transactions (invoice/DEA-222). In a borrowing and payback scenario, the pharmacy must have two transaction records: one record documenting receipt of the products and one record documenting the return of the product. The same documentation must be maintained by the pharmacy loaning the product. Intra-store transfers must also be recorded/documented.*

E.15 Vacuum Tube Delivery Systems [20 CSR 2220-2.800]

Vacuum tube systems may be used to deliver medication if:

- The system is designed and engineered to ensure drug security and to ensure that drugs are correctly and efficiently delivered;
- The system is dedicated solely to delivering drugs from within a licensed pharmacy and cannot be combined or attached to any other systems. Drugs may only be delivered to one destination/point outside the pharmacy. The system cannot have multiple or switchable drug delivery stations;
- The recipient's identification is verified before drugs are delivered; and
- The pharmacy maintains a direct and identifiable line of sight with the consumer. Alternatively, a video camera and audio system may be used to identify consumers. The video monitor and audio system must be in good working order or use must be discontinued until corrections/repairs are made. At a minimum, video monitors must be at least twelve inches (12") wide. Backlighting or other factors that may inhibit video/audio performance must be considered.

Vacuum tube systems must allow pharmacy personnel and the consumer to communicate effectively both orally and in writing. The tube system must be turned off and medication may not be delivered if the pharmacy is closed or when there is no pharmacist on duty. [*See 20 CSR 2220-2.800(2) for additional requirements for vacuum systems installed before September 1, 1988].*

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SECTION F: COMPOUNDING

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F.1 General Requirements

A Class D pharmacy permit (Non-Sterile Compounding) is required for pharmacies performing non-sterile compounding in batch quantities using bulk active ingredients. A Class H pharmacy permit is required for sterile compounding. Rule [20 CSR 2220-2.400] defines compounding as:

> *The preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding also includes the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.*

The Board does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (i.e.- Benzaclin, Benzamycin, etc.). However, the use of compounding kits that include the compounding ingredients is considered compounding (i.e.- CutisPharma First Kits). Licensees using compounding kits that include the compounding ingredients must comply with the Board's compounding rules, including, completion of the compounding log. The Board does not consider these kits to be commercially-available so a pharmacy may still compound these products without using the kit.

Pharmacies may not compound products that have been withdrawn from the market due to safety or effectiveness.

> *As defined by the Board's rules, compounding does not include incorporating a flavoring agent. However, licensees should indicate that the product was flavored on the patient container and the flavoring added must be documented in the prescription record. The flavoring of an OTC product without a prescription is not allowed. Additionally, licensees may not flavor a prescription dispensed by another pharmacy.*

F.2 Prescription Requirements

Except as otherwise provided by law, **licensees may only dispense compounded products pursuant to a prescription**. Licensees may not offer compounded products to other pharmacies, practitioners or commercial entities for subsequent resale or administration. [20 CSR 2220-2.400(12)] Licensees may, however, dispense a compounded product for a prescriber to administer in his office if a valid prescription has been received for the individual patient. Compounding for office stock is prohibited.

Licensees may compound drugs in "limited quantities" prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. For purposes of 20 CSR 2220-

2.400, a "limited quantity" is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded products intended for external use (i.e.- creams, ointments, lotions or liniments). While advance preparation is allowed, a prescription is required for dispensing. *[See rule 20 CSR 2220-2.200(16) for emergency exemptions]*.

F.3 Commercially Available Products

Pharmacists may not compound products that are commercially available or that are essentially copies of commercially available products. [20 CSR 2220-2.400(9)]. "Essentially copies" include different dosage forms (i.e.- suspension vs. solution, tablet vs. capsule). Missouri law recognizes the following exemptions:

- A commercially available product may be compounded if there is sufficient documentation of a specific medical need for the prescription. [20 CSR 2220-2.400(9)]. The "specific medical need" is the medical reason why the commercially available product can not be used. Cost or convenience are insufficient reasons. "Sufficient documentation" is considered to be either a prescription documenting the specific medical need or a notation in the pharmacy's records that verbal or other documentation of the specific medical need was received. Notations should include the name of the person verifying the medical need, the date, and the specific medical need/reason given.
- A commercially available product may be compounded if the product is temporarily unavailable due to problems other than safety or effectiveness (i.e.- a back order). Licensees should describe and document unavailability in the prescription record. [20 CSR 2220-2.400(9)]. The Board recommends documenting the dates of unavailability and retaining any documentation/communication from the manufacturer/distributor showing the unavailability. Licensees must stop compounding the product once the commercially-available product returns to the market.

F.4 Dispensing

The dispensing pharmacist must ensure that compounded products have been properly prepared, labeled, controlled, stored, dispensed and distributed. [20 CSR 2220-2.400(8)] Before release, the pharmacist must visually inspect bulk drug substances and all finished products for container-closure integrity, visible particulates or other foreign matter/visual defects.

For quality purposes, the dispensing pharmacist must also ensure that:

1) Each person assisting in compounding is capable and qualified to perform their assigned duties;
2) All ingredients have their expected identity, quality and purity. Drug components must meet compendial standards or the pharmacy must maintain a certificate of analysis on file when bulk drug substances are involved;
3) Reasonable assurance exists that compounding processes/procedures are always carried out by pharmacy staff as intended or specified; and
4) Compounding conditions/procedures are adequate for preventing mix-ups or other errors.

In addition to other labeling requirements, the actual name of each active or therapeutic ingredient contained in a compound must be listed on the patient's prescription container (i.e.- labels that

indicate only "magic mouthwash" are non-compliant.) [20 CSR 2220-2.400(7)(F)]. Auxiliary labels may be used to meet this requirement.

F.5 Beyond-Use Dates

Batched compounded products must be assigned a "beyond-use date" after which a compounded preparation should not be used. [20 CSR 2220-2.400(7)(A)6.] The beyond-use date must be determined from the date the preparation is compounded. Licensees should use their professional judgment in determining appropriate beyond-use dates. Because compounded products are intended for immediate administration or following short-term storage, beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products. [20 CSR 2220-2.400(4)]. Licensees may be asked to explain or support their rationale for assigning a beyond-use date.

> *Compounds that are not picked up by the patient and are returned to stock are considered batched and must be assigned a batch number and a beyond-use date in the compound log and on the label.*

F.6 Standards/Management [20 CSR 2220-2.400(6)]

Proper controls must be maintained over drug products/ingredients, containers and container closures to prevent contamination. Drug products, ingredients, containers and container closures may not be reactive, additive or absorptive in any way that would alter the safety, identity, strength, quality or purity of the compounded product beyond the desired result. Non-drug substances must also be free of contaminants and maintain full potency.

Container systems must be stored and used in a manner that will adequately protect against foreseeable deterioration or contamination. Compounding materials must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. Excess compounded products must be stored and accounted for under conditions dictated by their composition and stability. Excess products must be labeled with the name of the drug(s), an in-house lot number and the beyond-use date. [20 CSR 2220-2.400(6)].

> *For bulk ingredients that do not bear an expiration date, the pharmacy is encouraged to contact the manufacturer to determine the actual expiration date. If one is not provided, the pharmacy is encouraged to have a procedure for establishing an in-house expiration date for the ingredient.*

Pursuant to 20 CSR 2220-2.400(8)2., drug components must meet compendial standards (i.e.- USP, NF) or a certificate of analysis must be maintained on file when non-compendial bulk drug substances are used.

F.7 Facilities/Equipment [20 CSR 2220-2.400(5)]

Compounding area(s) must be sanitarily maintained at all times. Compounding areas must be free of infestation and trash must be disposed of in a timely manner.

Compounding equipment must be adequately and appropriately designed for the activities performed. Equipment surfaces may not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired. [20 CSR 2220-2.400(6)(E)]. Equipment must be appropriately located near the facility's operations to allow for proper use, cleaning and maintenance. [20 CSR 2220-2.400(5)(C)].

If drugs with special contamination precautions are used (i.e.- penicillin), appropriate measures must be utilized to prevent cross-contamination. [20 CSR 2220-2.400(5)(B)]. Appropriate measures may include, but may not be limited to, dedicating or adequately cleaning equipment.

F.8 Quality Control

Pharmacies are required to establish and maintain appropriate quality control measures over compounding methods. [20 CSR 2220-2.400(7)] Quality control measures must include:

1. Methods for compounding to ensure finished products have the identity, strength, quality and purity they purport or are represented to possess, and;
2. A description of the compounding process and the order for adding drug products/ingredients, if necessary.

Pharmacies must develop and maintain an outcome related drug monitoring system for evaluating the quality of compounding services. At a minimum, the monitoring system must evaluate/track infection rates, adverse drug reactions, recalls and prescriber/client complaints.

F.9 Compounding Log

Pharmacies must maintain a compounding log separate from the prescription that includes/records [20 CSR 2220-2.400(7)(A)]:

1) The compounding method used;*
2) The compounding date;
3) Identity of the compounding pharmacist;
4) A listing of the drug products/ingredients and their amounts by weight or volume;
5) Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding (i.e.- recipe/formula cards);*
6) The source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and
7) A prescription number/readily retrievable unique identifier for the compound.

***** *This information may be stored separately in the pharmacy's records, provided the records are immediately retrievable.*

> *The Board has observed instances of pharmacists compounding with expired ingredients. In many instances, the expired date was recorded in the compounding log signed by the pharmacist. Pharmacists must review log entries before signing to ensure information has been properly recorded. Additionally, licensees should take proactive steps to identify and remove all outdated/expired drugs and ingredients.*

F.10 Recalls

A recall must be initiated if a compounded product is deemed to be misbranded or adulterated. [20 CSR 2220-2.400(8)(C)]. In the event of a recall, the pharmacy must notify the prescriber of: 1) the nature of the recall, 2) the problem(s) identified and 3) any recommended action(s). If the compounded product could potentially cause patient harm, the same recall notification must be provided to the patient. Recall(s) must be reported to the Board in writing within three (3) business days.

> *Prescribers may be notified verbally or in writing. Licensees should exercise their professional judgment when determining notification methods. The Board recommends retaining proof of the date and manner of the recall/notification in the pharmacy's records.*

F.11 Over The Counter Products (OTC)

Compounding may only be done by prescription, regardless of the type of product (i.e.- OTC, herbal products, etc.). [20 CSR 2220-2.400(10)] Accordingly, licensees may only alter, change or modify an OTC product by prescription. Flavoring an OTC product by incorporating a flavoring agent constitutes a change/modification that requires a prescription.

F.12 Advertising/Solicitation

Licensees may advertise or provide information regarding the availability of compounding services and the type of compounding offered. However, licensees may not compare compounded products to commercially available products or make specific claims without supporting data (i.e.- designating a product as slow release). [20 CSR 2220-2.400(12)] Alternatively, licensees may not attempt to solicit business by making specific claims about compounded products without analytical data to support the claims for each product. Licensees must produce data for their specific product and may not rely on data obtained from other sources.

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SECTION G: STERILE COMPOUNDING

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G.1 Sterile Compounding

Class H Sterile compounding pharmacies are required to comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board, including, rule 20 CSR 2220-2.200 (Sterile Pharmaceuticals). Sterile compounders must also comply with 20 CSR 2220-2.400 which establishes standards of practice for all compounding pharmacies. *See Section F for additional compliance information for 20 CSR 2220-2.400.* Compliance with 20 CSR 2220-2.200 and 20 CSR 2220-2.400 is mandatory for all pharmacies holding a Class H (Sterile Compounding) pharmacy permit even if the pharmacy is not currently providing sterile compounding services.

The Board anticipates reviewing its sterile compounding rules in 2013 and will consider proposals to adopt USP 797. Interested parties should monitor the Board's website for future meeting dates and agenda topics.

> *The Board has determined that compounding bladder irrigation solutions constitutes sterile compounding that requires compliance with 20 CSR 2220-2.200 and a Class-H Sterile Compounding permit.*

G.2 Prescription Requirements

As with non-sterile compounding, pharmacies may only dispense compounded products pursuant to a patient specific prescription. [20 CSR 2220-2.400]. Drugs may be compounded in "limited quantities" prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. While advance preparation is allowed, **a prescription is required prior to dispensing**.

For purposes of 20 CSR 2220-2.400, a "limited quantity" is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded products intended for external use (i.e.- creams, ointments, lotions or liniments).

G.3 Compounding for Office Use

Sterile compounds may not be sold or dispensed to practitioners or other prescribers for office use. [20 CSR 2220-2.400(1), (12)]. This includes hospitals, surgery centers, etc. Once again, a patient specific prescription is required prior to dispensing. **Compounding for office use without a patient specific prescription constitutes grounds for discipline which may include REVOCATION or SUSPENSION of your pharmacy license.** *Note: Compounding for office use may also constitute manufacturing under federal law and require a Missouri drug distributor license.*

G.4 Commercially Available Products

Generally, Missouri law prohibits licensees from compounding products that are commercially available or that are essentially copies of commercially available products. "Essentially copies" includes different dosage forms (i.e.- suspension vs. solution, tablet vs. capsule).

Licensees may only compound a commercially available product:

- If the product is temporarily unavailable due to problems other than safety or effectiveness (i.e.- on back order). Unavailability must be documented in the pharmacy's records. [20 CSR 2220-2.400(9)]. *Note: Once the commercially available product is available, the pharmacy must stop compounding it;*
- If a "specific medical need" for the prescription exists. [20 CSR 2220-2.400(9)]. The "specific medical need" is deemed to be the ***medical reason*** why the commercially available product can not be used. The nature of the "specific medical need" must be documented on the prescription or otherwise documented in the pharmacy's prescription records. [20 CSR 2220-2.400(9)]. Cost or convenience are generally insufficient to establish a "specific medical need".

Once again, **compounding commercially available products in violation of Missouri law may result in disciplinary action by the Board.**

G.5 Policies & Procedures

Pursuant to 20 CSR 2220-2.200(2), Class H sterile compounding pharmacies must maintain a policy and procedure manual that addresses all aspects of sterile compounding performed by the pharmacy. Policy & procedure manuals should be regularly reviewed and updated to ensure appropriate practices. At a minimum, manuals must be reviewed annually. [20 CSR 2220-2.200(2)]. **Policy and procedure manuals and documentation of the annual review will be required during inspection**.

> *Board inspectors continue to observe instances of incomplete or outdated manuals. In other cases, pharmacy staff are unaware of recent policy/procedure changes. Manuals should be accessible to and reviewed by all pharmacy staff, including, new hires. Staff review is also recommended after any substantive change or modification to sterile compounding procedures or a breach in aseptic technique.*

G.6 Training

Due to the specialized nature of sterile compounding, training of pharmacy personnel is essential to ensuring patient safety. Rule 20 CSR 2220-2.200 contains detailed sterile compounding training and assessment requirements. Licensees should review the rule to ensure pharmacy staff are properly **trained and assessed at regular intervals**.

At a minimum, staff engaged in preparing sterile products must receive suitable didactic and experiential training in sterile compounding procedures. [20 CSR 2220-2.200(3)]. Staff engaged in preparing Risk Level 3 products must also have specific education and training in Risk Level 3

products/procedures. Additionally, a competency assessment must be conducted for all staff preparing Risk Level 2 or Risk Level 3 products via process simulation. The assessment must evaluate competence in all Risk Level 2 procedures and, if applicable, Risk Level 3 procedures. [20 CSR 2220-2.200(3)(B), (C)].

In addition to the required training and competence assessment, pharmacy staff must pass a process validation of aseptic techniques before compounding sterile products. The validations must include manipulations in all risk levels performed by the individual being assessed. **Process validations must be completed annually** and whenever:

- The pharmacy's quality assurance program yields an unacceptable result, or;
- Microbial growth is detected.

If microbial growth is detected after process validation, **the entire sterile process must be evaluated, corrective action taken and the process simulation test performed again**.

> *Inspectors continue to observe instances where training is not properly documented and/or the required annual process validation was either untimely or not conducted. Licensees should establish procedures for annually tracking process validation dates. Documentation of the required training and competency assessment must be maintained in the pharmacy's records for two (2) years and readily retrievable during inspection.*

G.7 Facilities & Equipment

Proper facility and equipment maintenance is vital to ensuring patient safety. Regular cleaning and disinfection must be conducted to prevent contamination and ensure sterility. Licensees should review 20 CSR 2220-2.200(5) for specific facilities and equipment requirements.

Licensees are reminded of the following rule requirements:

- Eating, drinking and smoking are prohibited in the controlled area.
- Ingredients and containers must be inspected for defects, expiration and integrity before use.
- Workbenches/hoods must be recertified every six (6) months and when moved. *Note: This is a common inspection violation.* Recertification documentation must be maintained in the pharmacy's records.
- Risk Level 2: The controlled area must meet Class 10,000 clean room standards. Floors must be disinfected daily, equipment surfaces weekly and walls monthly.
- Risk Level 3: Sterile products must be prepared in a Class 100 workbench, a Class 10,000 clean room, a Class 100 clean room or within a positive pressure barrier isolator. Floors must be disinfected daily. Equipment surfaces, walls and ceilings must be disinfected weekly.
- Access to Risk Level 3 clean rooms must be limited to individuals preparing sterile products. [20 CSR 2220-2.200(5)(C)].
- Daily refrigerator and temperature logs/recordings must be completed and maintained. [20 CSR 2220-2.200(9)].

- Non-sterile equipment that will come in contact with the sterilized final product must be sterilized before introduction in the clean room. [Risk Level 3]
- Proper garb/apparel must be used in the controlled area for Risk Level 2 & 3 products as provided in 20 CSR 2220-2.200(6).

> *Inspectors have encountered licensees improperly assigning sterile product risk levels. Licensees should review Missouri's rules to ensure compliance. When in doubt, the Board recommends assigning and utilizing procedures for the higher risk level.*

G.8 End Product Testing

End product testing is key to verifying and ensuring consistent sterility. 20 CSR 2220-2.200(12) contains mandatory end product testing requirements for all risk levels. Licensees should review the rule and the pharmacy's policies/procedures to ensure compliance.

Licensees are reminded of the following:

- A **pharmacist** must verify that each sterile product was accurately compounded prior to release. Final products must also be inspected for container leaks, integrity, solution cloudiness, phase separation, particulates, appropriate solution color and solution volume. [20 CSR 2220-2.200(12)(A)]. Final verification may not be delegated to pharmacy technicians or non-pharmacists.
- Risk Level 3: All Risk Level 3 products must be tested for sterility, pyrogens, and endotoxins. End product sterility testing must be conducted for a statistically valid sample of each sterile compounding product batch. USP Chapter 71 offers guidance on proper sample size. Parenteral sterile products must also be tested for pyrogens and endotoxins according to recommended USP methods. Products with beyond-use dates greater than 30 days must be tested for potency. [20 CSR 2220-2.200(12)(C)].
- Risk Level 3 sterile products compounded from nonsterile components **must be quarantined** pending end-product testing results in accordance with USP. [20 CSR 2220-2.200(12)(C)]. USP Chapter 71 requires sterility tests to be incubated for 14 days. Risk Level 3 products compounded from nonsterile components must be quarantined for the full 14 days. [20 CSR 2220-2.200(12)(C)].

20 CSR 2220-2.200(12)(D) authorizes emergency dispensing of Risk Level 3 products pending test results if the product is needed for immediate administration and no alternative product is available. Releasing Risk Level 3 products prior to the USP required 14-day incubation period for sterility testing is considered emergency dispensing and requires prescriber notification/approval. Once again, **the prescriber must be notified of the early release and approve the emergency dispensing**. [20 CSR 2220-2.200(1)(O)]. Prescriber approval and the need for emergency dispensing must be documented in the pharmacy's records. Separate prescriber authorization is required for each emergency dispensing. [20 CSR 2220-2.200(1)(O)].

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SECTION H: RECORDS

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H.1 Approved Systems:

Pharmacies must designate a primary record keeping system that may either be a manual record system or an electronic data processing system (EDP). [20 CSR 2220-2.010(2)]. All of the pharmacy's dispensing activities must be recorded in the designated system.

H.2 Manual Systems

If a manual system is selected, the pharmacy must maintain the following:

- A separate prescription file for Schedule I and II controlled substance prescriptions;
- A separate prescription file for Schedule III, IV and V controlled substance prescriptions; and
- A separate file for all other non-controlled drug prescriptions. [20 CSR 2220-2.010(3)-(4)]

Manual systems must allow for consecutive numbering of prescription hard copies. [20 CSR 2220-2.010(2)]. Additionally, the following information must be recorded on the reverse side of the prescription for each refill:

- The date the drug, medicine or poison was dispensed;
- The dispensing pharmacist's initials; and
- The amount of drug dispensed to the patient, if different from the face of the prescription.

[20 CSR 2220-2.010(3)]

Prescription hard copies must be filed by either the prescription label number or by a unique readily retrievable identifier.

H.3 Electronic Systems [20 CSR 2220-2.080]

If an electronic system is designated, the system must allow for the separate identification/retrieval of Schedule I and II controlled substance prescriptions, the separate identification/retrieval of Schedule III-V controlled substance prescriptions and the separate identification/retrieval of other non-controlled drug prescriptions. Required prescription hard copies must be stored in a three-file system as listed in section H.2

Electronic Data Processing ("EDP") systems must be able to store and retrieve [20 CSR 2220-2.080(2)]:

1) A prescription label number that is linked to the unique readily retrievable identifier;
2) The original prescription date, expiration date, or both;
3) The original filling date;
4) The patient's full name;
5) The prescriber's full name;
6) The name of the drug, medicine or poison dispensed;
7) The quantity dispensed on each fill/refill;

8) The initials or code of the pharmacist responsible for inputting or reviewing the original prescription or refill data;
9) The initials or code designation of the dispensing pharmacist for each refill;
10) The number of authorized refills or dispensable units remaining, and;
11) If a new prescription is transmitted by phone, whether generic substitution is allowed.

For controlled substances, the EDP must also document:
1) The prescriber's address and DEA number, and;
2) The patient's address.

Information may only be entered into the EDP system by a licensed pharmacist or a licensed/registered individual under the direct supervision of the pharmacist. [20 CSR 2220-2.080(1)]. The pharmacist is personally responsible for the accuracy of information inputted. [20 CSR 2220-2.080(1)]. The pharmacy must maintain a bound logbook or separate EDP verification file (i.e.- §the pharmacist signature log). [20 CSR 2220-2.080(5)]. All dispensing pharmacists must sign a statement in the logbook or verification file each day attesting that refill information has been entered into the system for the day and that the pharmacist has reviewed the information for accuracy. The logbook/file must be maintained at the pharmacy for a minimum of five (5) years after the dispensing date. [20 CSR 2220-2.080(5)].

The EDP system must contain a clear audit trail of any alterations made to the original prescription record including, but not limited to, a change in authorizing physician, total quantity or directions. If additional refills are authorized or added, the EDP system must indicate the method and source of authorization.

If a prescription is transferred from a pharmacy using an EDP system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the pharmacy, the prescription must be treated as a new record, showing the original date written and expiration date. [20 CSR 2220-2.080(9)].

***Production of Records**:* An EDP system must be capable of retrieving records within two (2) hours of a request by a Board inspector. Alternatively, the pharmacy must provide a computer terminal that will allow the inspector to immediately access the system. To allow review, the inspector may ask for code information. [20 CSR 2220-2.080(7)].

Drug Utilization: EDP systems must be able to retrieve a drug utilization listing for any drug for the previous twelve (12) months. Information must be available by specific drug product, patient name or practitioner. If requested by the Board, drug utilization reports must be provided within three (3) working days. [20 CSR 2220-2.080(12)].

H.4 Confidentiality

Prescription/dispensing records must be confidentially maintained in compliance with state and federal laws. Pharmacists and pharmacy permit holders have a duty to safeguard confidential records from any unauthorized use or review. The Board is aware that prescription records may be reviewed by third-party entities conducting audit/review functions (i.e.- pharmacy benefit managers, private consultants). Confidential records that are not within the jurisdiction of, or that do not relate to, a third-party entity must be securely maintained to avoid unauthorized access/disclosure.

Pharmacies should exercise caution in discarding or destroying drug containers. Information that could link the container to a specific patient should be removed before placing the container in trash receptacles or providing the container to a reverse distributor.

H.5 Retention Requirements

(The following chart summarizes selected record keeping requirements and is not a comprehensive listing. Licensees should review all relevant laws to ensure record keeping compliance.)

	PHARMACIST	
Continuing Education	Must be retained for two (2) reporting periods immediately prior to renewal	20 CSR 2220-2.100(10)
	PHARMACY	
Audit of Class-I Consultant Pharmacy Records	3 Years	20 CSR 2220-2.010(10)(A)3.
Compounding Log	2 Years	20 CSR 2220-2.400(7)(E)
Compounding Records	2 Years	20 CSR 2220-2.400(7)(E)
Controlled Substance Prescription Orders	5 years	§ 338.100, RSMo
Controlled Substance Transfer Records/DEA 222 forms	2 Years	21 CFR 1304.04
Controlled Substance Inventories	2 Years	§ 195.060, RSMo
Distribution Records	2 Years	20 CSR 2220-2.010(5)
Drug Invoices	2 Years	20 CSR 2220-2.010(5)
Electronic Data Processing System RPh Verification Logbook/file	5 years after dispensing	20 CSR 2220-2.080(5)(A)
Immunization Records	2-Years	20 CSR 2220-6.050(6)(D)2.
Immunization Protocol	8-Years after termination	20 CSR 2220-6.050(5)(B)
Medication Therapy Services (MTS) Protocol	7-Years	20 CSR 2220-6.080(7)(B)
MTS Patient Records *(generally)*	7-Years	20 CSR 2220-6.080(7)
Prescription Orders	5 Years	§ 338.100, RSMo
Sterile Compounding Records	2-Years	20 CSR 2220-2.200(9)(A)

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SECTION I: IMMUNIZATION BY PROTOCOL

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I.1 Authorized Activity

Missouri pharmacists may administer influenza, pneumonia, meningitis and shingles vaccines pursuant to a written protocol with a Missouri licensed physician. [20 CSR 2220-6.050]. Except for intern pharmacists as provided below, vaccinations may not be delegated to another person.

Immunization Requirements

Authorized Vaccines	✓ Pneumonia, shingles, meningitis & influenza vaccines ✓ Patient must be at least 12 years old
Qualification Requirements	✓ Notification of Intent filed with Board (Notifications **must** be filed online) ✓ Active Missouri RPh license ✓ Current CPR certification from the American Heart Association, American Red Cross or an equivalent body ✓ Completion of vaccine administration certificate program accredited by ACPE or an entity approved by the Board ✓ Protocol with a Missouri licensed physician
Notification Renewal	✓ Notification of Intent filed annually with the Board (Notifications must be filed online) ✓ Current CPR certification ✓ Two (2) CE hours (0.2 CEU) related to vaccinations within the prior twelve (12) months
Additional Compliance Requirements	Pharmacist must comply with: ✓ Manufacturer guidelines; ✓ Any applicable Centers for Disease Control (CDC) guidelines; and ✓ All state and federal laws governing Vaccine Information Statements and informed consent.
Intern Requirements	Licensed Missouri intern pharmacists may immunize if the intern: ✓ Has a current and active CPR certification ✓ Completed an immunizations certificate program accredited by ACPE or an entity approved by the Board ✓ Is under the direct supervision of a pharmacist qualified to immunize

I.2 Prescription Requirements

Within seventy-two hours (72) hours after administering a vaccine, the pharmacist must either obtain a prescription from the authorizing physician for the vaccine or create a prescription under the protocol physician's name documenting the dispensing, as authorized by protocol. [20 CSR 2220-6.050(7)(B)]

I.3 Protocol Requirements

To immunize, pharmacists must have a written protocol with a Missouri-licensed physician who is actively engaged in the practice of medicine. [20 CSR 2220-6.050(6)]. The authorizing physician's practice location must be no further than fifty (50) miles by road from the pharmacist, using the most direct route available. The protocol may be valid for no longer than one (1) year and must include:

1. *The identity and signature of the participating pharmacist and physician;*
2. *The time period of the protocol;*
3. *The identification of the vaccines which may be administered;*
4. *The identity of the patient or groups of patients who may be vaccinated;*
5. *The authorized routes and anatomic sites of administration;*
6. *Provisions for creating a prescription for each administration under the authorizing physician's name;*
7. *A course of action for addressing emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;*
8. *The length of time the pharmacist is required to observe a patient for adverse events following an injection;*
9. *Provisions for disposing of used and contaminated supplies;*
10. *The street addresses of the pharmacy or other locations where vaccines may be administered;*
11. *Record keeping requirements and procedures for notification of administration; and*
12. *Provisions for terminating the protocol at the request of any party at any time.*

A new protocol must be signed each year. Protocols do not have to be submitted to the Board, however, the protocol must be retained in the pharmacist's records for review/inspection for a minimum of eight (8) years after the protocol is terminated.

> *Amendments to the protocol must be signed by all participating pharmacists and prescribers. Signatures may be included on the original protocol or on a separate document that is attached to the protocol. A pharmacist may be added to an existing protocol if the protocol is signed by the newly added pharmacist and the authorizing physician(s).*

I.4 Records [20 CSR 2220-6.050(7)]

Pharmacists administering vaccines by protocol must document and maintain a record of:

1. *The name, address, and date of birth of the patient;*
2. *The date, route, and anatomic site of the administration;*
3. *The name, dose, manufacturer, lot number, and expiration date of the vaccine;*
4. *The name and address of the patient's primary health care provider, as identified by the patient;*
5. *The name or identifiable initials of the administering pharmacist, and;*
6. *Any adverse reaction and who was notified, if applicable.*

Vaccination records must be maintained for a minimum of two (2) years. If vaccines are administered on behalf of a pharmacy, records must be maintained at the pharmacy. If the vaccine is not being administered on behalf of a pharmacy, records should be maintained at an address identified in the protocol.

I.5 Notification Requirements

Licensees must comply with the following notification requirements [20 CSR 2220-6.050(8)]:

	Timeframe	Notification Requirements	Notification Method
Authorizing Protocol Physician	Within 72 hours after administration	✓ The identity of the patient ✓ The vaccine(s) administered ✓ The route of administration ✓ The anatomic site of administration ✓ The dose administered ✓ The date of administration	Within the pharmacist's discretion, however, documentation of the notification must be maintained.
Primary Care Provider *(If different from the authorizing physician)*	Within fourteen (14) days of administration	Same notification as authorizing physician	Must be in writing. May be transmitted electronically or by fax/mail. Documentation of notification required.
Adverse Events	Within twenty-four (24) hours after learning of the adverse event/reaction	The authorizing physician must be notified and the patient's primary care provider, if different. Notification must include a description of the adverse event/reaction and any other requirements mandated by protocol	The method of notification is within the pharmacist's discretion, however, documentation of the notification must be maintained.
State/Federal Entities	As required by law	As required by law	As required by law

For additional immunization compliance information, see the Board's Immunization Checklist on the Board's website at http://pr.mo.gov/boards/pharmacy/13863[1].pdf .

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SECTION J: ADMINISTRATION BY MEDICAL PRESCRIPTION ORDER

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J.1 Authorized Activity

Pharmacists may administer medication pursuant to a medical prescription order subject to the requirements below. [20 CSR 2220-6.040]. Except as provided for intern pharmacists, medication administration may not be delegated to another person.

Administration Requirements

Qualification Requirements	✓ Notification of Intent filed with Board (Notifications **must** be filed online) ✓ Active Missouri RPh license ✓ Current CPR certification from the American Heart Association, American Red Cross or an equivalent body ✓ Completion of drug administration certificate program accredited by ACPE or an entity approved by the Board ✓ A written policy and procedure manual covering all aspects of drug administration, including the disposal of used/contaminated supplies and handling of acute adverse events. The manual must be reviewed annually and available for inspection.
Notification Renewal	✓ Notification of Intent filed annually with the Board (Notifications must be filed online) ✓ Current CPR certification ✓ Two (2) CE hours (0.2 CEU) related to drug administration within the prior twelve (12) months
Additional Compliance Requirements	Pharmacists must comply with: ✓ Manufacturer guidelines ✓ Any applicable Centers for Disease Control (CDC) guidelines. ✓ All state and federal laws governing patient information statements and informed consent
Intern Pharmacist Requirements	Licensed Missouri intern pharmacists may immunize if the intern: ✓ Has a current and active CPR certification ✓ Completed an administration certificate program accredited by ACPE or an entity approved by the Board ✓ Interns must be under the direct supervision of a pharmacist qualified to administer drugs
Authorized Medication/Vaccines	As prescribed

J.2 Prescription Requirements

At a minimum, the prescription order must contain:

1) The prescriber's name;
2) The patient's name;
3) The name of the drug and dose to be administered;
4) The route of administration;
5) The date of the original order;
6) The date or schedule, if any, of each subsequent administration; and
7) A statement that the drug is to be administered by a pharmacist.

[20 CSR 2220-6.040(4)]

> *The Board's inspectors routinely observe non-compliance in this area. To be valid for administration, the prescription must indicate the prescribed route of administration and indicate that the drug is to be administered by a pharmacist. A pharmacy may contact the prescriber to get authorization to add these items to a prescription. Authorization must be documented in the pharmacy's records.*

J.3 Records

The following records must be maintained for each administration:

1) The patient's name, address, and date of birth;
2) The date, route, and anatomic site of the administration;
3) The name, dose, manufacturer, lot number, and expiration date of the drug;
4) The name and address of the patient's primary health care provider, as identified by the patient;
5) The name or identifiable initials of the administering pharmacist; and
6) The nature of any adverse reaction and who was notified, if applicable.

[20 CSR 2220-6.040(6)]

Administration records must be maintained by the pharmacist separate from the pharmacy's prescription records. Records must be maintained securely and confidentially for a minimum of two (2) years.

J.4 Reporting/Notifications

Administration Notification Requirements [20 CSR 2220-6.040(7)]

	Timeframe	Notification Requirements	Notification Method
Prescriber	Within 72 hours after administration	✓ The identity of the patient ✓ The name of the drug administered ✓ The route of administration ✓ The anatomic site of administration ✓ The dose administered ✓ The date of administration	Notification must be documented in the pharmacy's records
Adverse Events	Within twenty-four (24) hours after learning of the adverse event/reaction	The prescriber must be notified	Notification must be documented in the pharmacy's records
State/Federal Entities	As required by law	As required by law	As required by law

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SECTION K: MEDICATION THERAPY SERVICES

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K.1 General Requirements

Pursuant to § 338.010, a Missouri licensed pharmacist may perform "medication therapy services" after obtaining a certificate of medication therapeutic plan authority from the Board. "*Medication therapy services*" are defined in rule 20 CSR 2220-6.060(1)(F) as:

> *[T]he designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has* ***authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol.***

Medication therapy services *("MTS")* are different from "medication therapy management." As commonly defined, medication therapy management includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. Medication therapy management is within the scope of the "practice of pharmacy" and can be performed by any Missouri licensed pharmacist (i.e.- Medicare Part D medication therapy management). A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy.

Modification of drug therapy includes, but is not limited to,:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration

Modification does not include dispensing a drug/device pursuant to a valid prescription from an authorized prescriber or selecting a generic substitution as authorized by § 338.056. Additionally, "medication therapy services" do not include administering medication by prescription order pursuant to 20 CSR 2220-6.040 or administering vaccines by protocol pursuant to 20 CSR 2220-6.050.

Prior to performing MT services, a pharmacist must have:

- A MT certificate issued by the Board, and
- A protocol with a Missouri licensed physician who is actively practicing medicine in Missouri.

K.2 Scope of Authority

Licensees holding a current MT certificate may perform medication therapy services as authorized by their governing protocol. However, the following restrictions/prohibitions apply:

- **Pharmacists may not initiate or modify any controlled substance.**

- **Pharmacists may not independently prescribe.** Instead, medication may only be modified or initiated as authorized by a written protocol with a Missouri physician.
- **MT services may not be delegated.** Pursuant to § 338.010, MT services may only be performed by a pharmacist who holds a MT certificate. Pharmacy technicians and intern pharmacists may assist in providing services under the supervision of a pharmacist. However, technicians and interns may not initiate or modify drug therapy or perform any act that requires the professional judgment of a pharmacist.

K.3 Certificate Requirements

All pharmacists performing MT services in Missouri are required to have a MT certificate issued by the Board. An MT certificate is not required to administer medication by prescription order pursuant to 20 CSR 2220-6.040 or to administer vaccines by protocol under 20 CSR 2220-6.050. For detailed information on obtaining a MT certificate, see 20 CSR 2220-6.070 and the Board's Medication Therapy Services Q&A.

MT certificate holders must complete 6 hours of continuing education in courses/programs related to medication therapy management each pharmacist biennial renewal period. The required continuing education may be used to satisfy Missouri's biennial pharmacist continuing education requirements.

Residents: Pharmacy residents must satisfy all MT certificate requirements. However, the Board does not have jurisdiction over hospital inpatient pharmacy practice and is legally reviewing the applicability of the MTS rules to pharmacy residents practicing in a hospital inpatient setting. In the interim, licensees should consult with legal counsel to ensure compliance.

K.4 Protocol Requirements

Prior to performing MT services, pharmacists must have a written protocol with a Missouri licensed physician who is actively practicing medicine in the state of Missouri and whose practice location is no more than fifty (50) miles by road from the pharmacist.

The Board does not have a form or recommended protocol. However, protocols should clearly delineate the pharmacist's scope of authority. As detailed in 20 CSR 2220-6.080(4), protocols must include:

- The names and signatures of the participating physician(s) and pharmacists(s);
- The effective date of the protocol;
- A description of MT services the pharmacist is authorized to provide. Authorized MT services must be within the skill, education, training and competence of the authorizing physician and pharmacist;
- A list of clinical conditions, diagnoses and diseases included in the written protocol and the type of medication therapy allowed in each case;
- The specific drugs or drug categories included in the protocol;
- A statement of the methods, procedures, decision criteria and plan the pharmacist is to follow when providing MT services;
- A description of any authority granted to the pharmacist to administer medication;
- A list of drugs the pharmacist is authorized to administer;
- A description of drug therapy related patient assessment procedures or testing the pharmacist may order or perform;

- Procedures for documenting the pharmacist's MT decisions;
- Procedures and requirements for communicating and reporting MT decisions to the authorizing physician;
- Criteria for timely communication between the pharmacist and authorizing physician;
- A statement prohibiting the pharmacist from delegating the responsibility of MT services;
- Methods for physician review of MT activities;
- Provisions allowing the authorizing physician to access patient records;
- Mechanisms and procedures that allow the authorizing physician to override, rescind or otherwise modify the protocol;
- Emergency response procedures the pharmacist is authorized to follow to address emergency situations, including, anaphylactic or other adverse medication reactions, adverse needle sticks or other adverse events;
- All notification requirements required by 20 CSR 2220-6.080(5) (*see below);* and
- An address where required records will be maintained.

Practicing outside of the scope of authority granted by protocol constitutes grounds for discipline under § 338.055.

Protocols must be signed and dated by both the authorizing physician and pharmacist. If a protocol includes multiple physicians and pharmacists, a separate protocol is not required for each participating physician/pharmacist if all authorizing physicians and pharmacists sign and date a statement agreeing to be governed by the terms of the protocol.

Modifications/amendments to the protocol must be documented in writing and signed and dated by both the pharmacist and the authorizing physician prior to implementing the modification/ amendment. Protocols may be immediately rescinded by the authorizing physician or pharmacist with or without cause, provided the rescission is documented in writing.

Protocols should be regularly reviewed to ensure appropriateness of services. At a minimum, protocols must be reviewed and signed annually by the authorizing physician and pharmacist. The annual review date must be documented on the written protocol.

Protocols do not have to be filed with the Board. Instead, protocols must be retained and provided to the Board or the Board's designee upon request. Both the pharmacist and authorizing physician must retain signed copies of the written protocol in their records for 8 years after the protocol is terminated.

Pharmacy Residents: In lieu of an individual protocol, a pharmacy resident may perform MT services under the written protocol of another Missouri pharmacist if:

- The resident holds a MT certificate from the Board,
- The resident is enrolled in a residency training program accredited by the American Society of Health System Pharmacists (ASHP) or a residency training program with a valid application for accreditation pending with ASHP, and;
- The resident is providing MT services under the supervision of a Missouri pharmacist with a current MT certificate issued by the Board.

The Board does not have jurisdiction over hospital inpatient pharmacy practice and is legally reviewing the applicability of the MTS rules to pharmacy residents practicing in a hospital inpatient setting. In the interim, licensees should consult with legal counsel to ensure compliance.

K.5 Prescription Orders

To provide MT services for a specific patient, a pharmacist must obtain a prescription order from their protocol physician authorizing the pharmacist to perform MT services. Pursuant to 20 CSR 2220-6.080(2)(A), the prescription order must include:

- The patient's name, address and date of birth;
- The date the prescription order was issued;
- The clinical indication for MT services (i.e.- the patient's clinical condition, diagnosis or disease);
- The authorizing physician's name and address; and
- The length of time for providing MT services, if less than one (1) year.

Prescription orders for MT services must be in the 2-line format required by § 338.056. Prescription orders must be maintained in the patient record required by 20 CSR 2220-6.080(2)(D) along with documentation of any changes or alterations made to the prescription order based on contact with the prescriber *(see K.9 below)*. Prescription orders maintained in compliance with 20 CSR 2220-6.080(2) will be deemed to comply with the general medication prescription requirements of 20 CSR 2220-2.018.

Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically or in writing.

K.6 Documentation of MT Services

Pharmacists must document and maintain an adequate patient record of MT services provided for each patient. At a minimum, the patient record must include:

- The patient's name, birthdate, address and telephone number;
- The dates of any patient visits/consultations and the reason for the visit/consultation;
- Any pertinent assessments, observations or findings;
- Any diagnostic testing recommended or performed;
- The name of any medication or device modified;
- The strength, dose, dosage schedule or route of administration of any medication modified or administered;
- Referrals to the authorizing physician;
- Referrals for emergency care;
- Any contact with the authorizing physician concerning the patient's treatment or MT services plan;
- Any informed consent for procedures, medications or devices; and
- Any consultation with other treatment providers for the patient and the results of the consultation.

K.7 Therapy Modifications

As provided by 20 CSR 2220-6.080(6), pharmacists with a MT certificate may modify drug therapy or device usage as provided in the governing protocol. Pharmacists may only modify non-controlled medications. Pharmacists may not modify any controlled substance. [20 CSR 2220-6.080(6)(B)]. If the modification results in a drug/device being dispensed, the modification must be documented by creating a prescription for the medication or device modified in the pharmacy's prescription records [20 CSR 2220-6.080(6)(A)]. The prescription must be under the authorizing physician's name. All therapy modifications made by the pharmacist must be documented in the patient's record.

> *Prescriptions generated by a pharmacist pursuant to 20 CSR 2220-6.080(6)(A) may be dispensed by a licensed pharmacy. Pharmacist's may not sign their name or the physician's name to a written prescription generated under 20 CSR 2220-6.080(6). Instead, modifications may be verbally submitted to the other pharmacy or e-prescribed in accordance with governing law.*

K.8 Notifications

20 CSR 2220-6.080(5) requires the following notifications:

TYPE	RECIPIENT	TIMEFRAME
Anaphylactic or adverse medication reactions, adverse needle sticks or other adverse events	Authorizing physician or physician's authorized designee	24-Hours
Therapy modifications	Authorizing physician or physician's authorized designee	24-Hours
Other notifications required by protocol	*As governed by protocol*	*As governed by protocol*

Notifications must be in writing unless otherwise authorized by the protocol physician. Pharmacists providing MT services for, or on behalf of, a health care entity may satisfy the notification requirements if the notification is recorded in a patient medical record that the health care entity is required to maintain under state or federal law.

Protocols may include more stringent notification requirements. Failure to comply with protocol requirements constitutes grounds for discipline.

K.9 Records

Records required by 20 CSR 2220-6.080 must be maintained as follows:

TYPE	TIMEFRAME
Patient records required by 20 CSR 2220-6.080(7)	7 years after termination of protocol
Protocols, including, protocol changes or amendments	8 years after termination of protocol
Prescription orders for MT services	7 years after termination of protocol
Other records required by protocol	As governed by protocol

Records may be maintained electronically provided the records are subject to retrieval and review by the Board of Pharmacy or the Board of Registration for the Healing Arts. Records maintained at a pharmacy must be produced during an inspection or investigation if requested by either Board or their authorized designees. Records not maintained at a pharmacy must be produced within three (3) business days of a request. Failure to maintain or produce records constitutes grounds for discipline.

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SECTION L: PHARMACY TECHNICIANS

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L.1 Registration Requirements

All pharmacy technicians must be registered with the Board. [§ 338.013, 20 CSR 2220-2.700] A pharmacy technician is defined as any person who assumes a supportive role or who is utilized to "perform routine functions. . .in connection with the receiving, preparing, compounding, distributing or dispensing of medication." [20 CSR 2220-2.700]. Additionally, "any person other than a pharmacist or permitholder who has independent access to legend drug stock on a routine basis" must be registered as a technician.

The pharmacist-in-charge is responsible for determining if an individual has "independent access" to drug stock. The Board has determined that the ability to access the pharmacy does not automatically require technician registration (i.e.- an employee/auditor has a key to the pharmacy). However, individuals who utilize their access to *independently* enter the pharmacy must be registered as a technician.

To be registered, an applicant must submit an application with the applicable fee and undergo a criminal history background check. Missouri does not currently impose minimum education or certification requirements for technician registration. However, technicians should be appropriately trained to perform the tasks delegated. *Note: Additional training is required for technicians performing/assisting in sterile compounding*. [20 CSR 2220-2.200(3)].

Applicants may begin working as a pharmacy technician if a completed registration application has been mailed to the Board. To be complete, the application must include an official fingerprinting receipt and the required fee. A copy of the application must be maintained on the premises of the pharmacy. [§ 338.013]. The Board also recommends that the pharmacy and applicant maintain proof of mailing.

> *Prescription delivery staff that are solely performing delivery functions do not have to be registered as technicians. However, adequate security procedures must be in place. Technician registration may be required if delivery staff are performing additional functions.*

L.2 Supervision/Allowed Activities

A pharmacy technician may assist in any area of pharmacy practice, including, receiving, preparing, compounding, distributing or dispensing prescriptions. [20 CSR 2220-2.700(1)]. However, technicians may not work independently and must be under the "direct supervision and responsibility" of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700]. Additionally, technicians may not counsel patients. All prescriptions prepared or compounded by a technician must be finally verified/checked by a pharmacist, including, reconstituted products.

Technicians may not perform any activity that requires the "professional judgment" of a pharmacist. [20 CSR 2220-2.700(1)]. Prohibited activities include, but are not limited to,:

- Final verification of a prescription before dispensing;
- Receiving or providing refill transfer information for controlled substance prescriptions [20 CSR 2220-2.120(1)(D)];
- Drug utilization review; and
- Patient counseling.

> *The Board has determined that technicians may accept written prescriptions from patients for dispensing when "no pharmacist is on duty." [20 CSR 2220-2.010(1)(B)]. However, technicians cannot take verbal prescription orders or fill, compound or prepare a prescription if the pharmacist is absent. Additionally, technicians cannot hand out, dispense or distribute prescriptions when no pharmacist is on duty, even if the prescription was previously checked by a pharmacist.*

L.3 Renewals

Technician registrations are valid for one (1) year and expire annually on May 31st. A technician may not work if his/her registration is not renewed by May 31st. [§ 338.013.5]. License status may be checked on the Board's website. Practicing without a valid registration and/or allowing unlicensed practice constitutes grounds for discipline. [§ 338.055.2(10)].

Technicians who fail to renew by May 31st may submit late renewal applications to the Board until June 30th. Although the Board will accept the renewal application, the individual cannot work after May 31st until his/her registration has been renewed by the Board. Applicants wishing to renew after June 30th will be required to submit a new technician registration application and undergo a new criminal history background check.

L.4 Reporting Technician Action [§ 338.013.10]

Hospitals and licensed pharmacies are required to report to the Board any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055. This requirement applies to any form of final disciplinary action, including, but not limited to, probation, suspension, demotion or reassignment. By statute, PICs must also report any technician who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055.

Written notice of technician action must be filed with the Board in writing within fifteen (15) days after the action. [20 CSR 2220-2.010(1)(P)]. Notifications must include:

- The name and permit number of the pharmacy;
- The name of the person making the notification;
- The technician's name and registration number;
- Date of action; and
- Reason for action.

Notification of Technician Action notices may be filed on the Board's website.

SECTION M: LONG-TERM CARE

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M.1 Licensure Requirements

A Missouri Class C pharmacy permit is required if a pharmacy:

- Provides prescription services to a long-term care ("LTC") facility, or
- Dispenses legend drugs/devices to patients residing in an LTC facility. [20 CSR 2220-2.140]

A Class C pharmacy permit is required before any prescriptions are dispensed to a LTC facility/ resident. As used in the Board's rules, a "long-term care facility" is defined as a "nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients." [20 CSR 2220-2.020(9)(C)]. Jails/prisons are considered to be LTC facilities for purposes of the Board's rules.

Pursuant to 20 CSR 2220-2.140(2), Class C pharmacies must have a policy and procedure manual that includes:

- Methods for timely dispensing medication;
- Procedures for notifying the facility when a medication is not readily available;
- Labeling requirements and policies;
- Policies/procedures for appropriate medication destruction and/or returning unused medication, as authorized by state and federal law; and
- Policies/procedures for securing, delivering, storing and handling emergency kits.

M.2 Authorized Dispensing

Licensees may dispense legend drugs to a LTC resident upon receipt of a prescription or upon receipt of a "*prescription drug order*." For purposes of LTC dispensing, a "*prescription drug order*" is defined as "an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device." [20 CSR 2220-2.140(5)].

Generic substitution is allowed if authorized by the prescriber. [20 CSR 2220-2.140(5)(B)]. Clear documentation of substitution authorization must be maintained, as required by 20 CSR 2220-2.018(1)(H) and 20 CSR 2220-2.080(2)(M).

Containers must meet minimum USP requirements, including, but not limited to, single unit, unit dose and unit-of-use containers. [20 CSR 2220-2.140(2)(C)]. If applicable, light sensitive packaging must be used. Internal liners must always be replaced before refilling the container. Personnel packaging drugs must wear gloves when handling individual tablets and capsules. If drugs are dispensed in a container other than the manufacturer's original container, the container must bear the manufacturer's expiration date or twelve (12) months, whichever is less. [20 CSR 2220-2.140(3)].

The Board is aware of packaging used by long-term care pharmacies that involve plastic liners housed within a hard plastic container. These liners must be changed on each initial and refill dispensing.

Pharmacies may maintain a separate file for LTC prescription drug orders, provided that a separate numbering system is used for prescription drug orders. [20 CSR 2220-2.140(5)(C)]. Pharmacies using interim dispensing systems must have records that clearly record these dispensings as any other new or refill dispensing. A pharmacy using a computer record keeping system must document interim dispensing in the computer system and may not use a manual record system to record them.

Under 20 CSR 2220-2.140(5)(D), if a pharmacy is dispensing to a long-term care facility pursuant to a nursing home order, then refills associated with the order are not valid for transfer.

M.3 Labeling

Containers dispensed to LTC facilities must comply with all state and federal labeling requirements. [20 CSR 2220-2.140(5)(D)]. However, Missouri law authorizes the following exceptions for unit-dose containers:

- The drug name/strength, control number, expiration date and manufacturer's name may be included on the package, and;
- The patient's name and directions do not have to appear on the container label if the LTC facility has a mechanism that will identify the medication each patient is to receive, the personnel administering the medication and the directions for administration. [20 CSR 2220-2.140(2)(B)].

A bubble card is not considered a unit-dose container and must bear a full prescription label.

In the event of a change in directions, a pharmacist may change the container label, however, the pharmacist must personally affix the revised label. Revised prescription labels may not be sent to the LTC facility for their staff to apply. [20 CSR 2220-2.140(2)(B)].

All drugs dispensed to a LTC facility must have an expiration date on the container.

M.4 Return, Reuse & Disposal:

Licensees may receive and reuse drugs from a LTC facility, if:

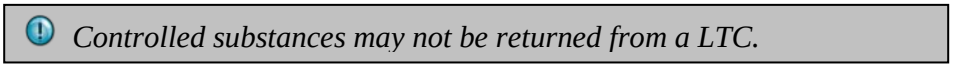
1) The medication was originally dispensed by the pharmacist or pharmacy to the institution/facility;
2) The pharmacist has assurance from a person at the institution/facility that is responsible for the medication that the drugs were stored in accordance with the manufacturer's recommendations and USP standards; and
3) There is an established mechanism to trace the expiration date and the manufacturer's lot number of the returned drugs.

[20 CSR 2220-3.040(2)]

Returned drugs from a LTC facility may be reused if:

1) The drug products are returned sealed in the original manufacturer's tamper-evident packaging;
2) The drug products were repackaged by a licensed pharmacy or an FDA registered repackager and are returned sealed in the repackager's tamper-evident packaging, or;
3) The drug products are returned in unit-of-use packaging and the unused portions can be separated and reused without any further repackaging.

Returned medication must be relabeled to provide accurate patient and prescription information. The original lot numbers, expiration date(s) or beyond-use date(s) may not be altered.



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RESOURCES

BOARD OF PHARMACY:

- Website
- Publications/Resources Page

Publications

- Certification of Medication Therapeutic Plan Authority Q&A
- Drug Distributor Compliance Guide
- Immunization/Administration Checklist
- Immunization FAQ
- Internet Practice
- Medication Therapy Services Compliance Guide
- Missouri Law Book
- Missouri Pharmacy Practice Guide
- Pharmacist-In-Charge FAQ
- Pharmacy Compliance Top 10
- Pharmacy Inspection Guide

Videos/Webinars

- 2012 A Review of Immunization/Administration Regulations
- 2012 BNDD Regulatory Update
- 2012 Compliance Keys for the PIC
- 2012 Compliance Keys For Drug Distributors
- 2012 Pharmacy Security & Drug Diversion Awareness
- 2012 Regulatory and Legislative Update

MISSOURI BUREAU OF NARCOTICS AND DANGEROUS DRUGS (BNDD)

- Website
- BNDD Newsletter/Publications
- Controlled Substance Guidelines for Pharmacies
- Mid-Level Practitioner & Controlled Substance Guidelines
- Missouri Changes to Prescriptions Guidelines

DRUG ENFORCEMENT ADMINISTRATION (DEA)

- DEA Website
- Controlled Substances Act
- DEA Rules
- DEA Pharmacist Manual
- DEA Statement on Agents of Prescribers